Final Progress Report for Research Projects Funded by Health Research Grants

Instructions: Please complete all of the items as instructed. Do not delete instructions. Do not leave any items blank; responses must be provided for all items. If your response to an item is "None", please specify "None" as your response. "Not applicable" is not an acceptable response for any of the items. There is no limit to the length of your response to any question. Responses should be single-spaced, no smaller than 12-point type. The report **must be completed using MS Word**. Submitted reports must be Word documents; they should not be converted to pdf format. Questions? Contact Health Research Program staff at 717-231-2825.

1. **Grantee Institution:** American College of Radiology

2. **Reporting Period (start and end date of grant award period):** 1/1/2011 – 12/31/2014

3. **Grant Contact Person (First Name, M.I., Last Name, Degrees):** Stephen M. Marcus, M.S.

4. **Grant Contact Person's Telephone Number:** 267-940-9403

5. **Grant SAP Number:** 4100054841

6. **Project Number and Title of Research Project:** #2 – Pennsylvania CT Dose Registry and Reduction Project

7. **Start and End Date of Research Project:** 1/1/2011 – 12/31/2014

8. **Name of Principal Investigator for the Research Project:** Mitchell Schnall, MD, PhD

9. **Research Project Expenses**.

   9(A) Please provide the total amount of health research grant funds spent on this project for the entire duration of the grant, including indirect costs and any interest earned that was spent:

   $ 738,274.96

   9(B) Provide the last names (include first initial if multiple individuals with the same last name are listed) of **all** persons who worked on this research project and were supported with health research funds. Include position titles (Principal Investigator, Graduate Assistant, Post-doctoral Fellow, etc.), percent of effort on project and total health research funds expended for the position. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name, First Name	Position Title	% of Effort on Project	Cost
Litt	Study Chair	20% each year	$96,254.00
Heckel	Protocol Assoc	1% Yr1	$ 543.94
Bauza	Image Tech	.05% Yr2	$ 52.60
Flamini	Image Analyst	1% Yr2	$ 1185.11
Mahon	Project Mgr	8% Yr 2; 1% Yr3	$ 12,851.30
Price	Image Tech	1% Yr 3	$ 888.40
Olson	Proj Mgr	9% Yr3; 28% Yr4	$ 50,808.04
Gimpel	Image Manager	.15% Yr3	$ 209.63
Apgar	Sr Director	1% Yr 4	$ 1,574.38
Daniels	Associate	14% Yr 4	$ 10,293.42
Marella	Programmer	1% Yr 4	$ 725.19
Wang	Proj Mgr-IT	4% Yr 4	$ 16,081.23
Kocabus	IT Support	25% Yr 4	$ 32,524.07
Corrie	System Support	16% Yr 4	$ 12,436.49
Fogel	Admin Mgr	16% Yr1; 6% Yr 2	$ 18,822.57
Ryan	IT Admin	21% Yr 2; 3% Yr 3	$ 31,694.86
Neelaphaur	IT Support	32% Yr 2; 21% Yr 3	$ 57,646.46

9(C) Provide the names of **all** persons who worked on this research project, but who *were not* supported with health research funds. Include position titles (Research Assistant, Administrative Assistant, etc.) and percent of effort on project. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name, First Name	Position Title	% of Effort on Project
Saini, Vipin	Radimetrics Project Manager	5
Schnall, Mitchell	Project Principal Investigator	2
Cook, Tessa	Co-investigator	2

9(D) Provide a list of **all** scientific equipment purchased as part of this research grant, a short description of the value (benefit) derived by the institution from this equipment, and the cost of the equipment.

Type of Scientific Equipment	Value Derived	Cost
None		

10. Co-funding of Research Project during Health Research Grant Award Period. Did this research project receive funding from any other source during the project period when it was supported by the health research grant?

Yes_____ No_____X____

If yes, please indicate the source and amount of other funds:

11. Leveraging of Additional Funds

11(A) As a result of the health research funds provided for this research project, were you able to apply for and/or obtain funding from other sources to continue or expand the research?

Yes_____ No_____X_____

If yes, please list the applications submitted (column A), the funding agency (National Institutes of Health—NIH, or other source in column B), the month and year when the application was submitted (column C), and the amount of funds requested (column D). If you have received a notice that the grant will be funded, please indicate the amount of funds to be awarded (column E). If the grant was not funded, insert "not funded" in column E.

Do not include funding from your own institution or from CURE (tobacco settlement funds). Do not include grants submitted prior to the start date of the grant as shown in Question 2. If you list grants submitted within 1-6 months of the start date of this grant, add a statement below the table indicating how the data/results from this project were used to secure that grant.

A. Title of research project on grant application	B. Funding agency (check those that apply)	C. Month and Year Submitted	D. Amount of funds requested:	E. Amount of funds awarded:
None	☐NIH ☐ Other federal (specify:_____) ☐ Nonfederal source (specify:_)		$	$

11(B) Are you planning to apply for additional funding in the future to continue or expand the research?

Yes_____ No_____X_____

If yes, please describe your plans:

12. Future of Research Project. What are the future plans for this research project?

It is anticipated that the results of this study will inform the American College of Radiology's Dose Index Registry's quality improvement efforts nationally.

13. New Investigator Training and Development. Did students participate in project supported internships or graduate or post-graduate training for at least one semester or one summer?

Yes_____ No___X_____

If yes, how many students? Please specify in the tables below:

	Undergraduate	Masters	Pre-doc	Post-doc
Male				
Female				
Unknown				
Total				

	Undergraduate	Masters	Pre-doc	Post-doc
Hispanic				
Non-Hispanic				
Unknown				
Total				

	Undergraduate	Masters	Pre-doc	Post-doc
White				
Black				
Asian				
Other				
Unknown				
Total				

14. Recruitment of Out-of–State Researchers. Did you bring researchers into Pennsylvania to carry out this research project?

Yes_____ No____X____

If yes, please list the name and degree of each researcher and his/her previous affiliation:

15. Impact on Research Capacity and Quality. Did the health research project enhance the quality and/or capacity of research at your institution?

Yes____X____ No_____

If yes, describe how improvements in infrastructure, the addition of new investigators, and other resources have led to more and better research.

The implementation of the eXposure software platform (described below) at our institution

during this project has led to numerous research and quality improvement projects concerning CT dose optimization.

16. Collaboration, business and community involvement.

16(A) Did the health research funds lead to collaboration with research partners outside of your institution (e.g., entire university, entire hospital system)?

Yes_____X____ No_____

If yes, please describe the collaborations:

The study involved researchers at multiple sites: University of Pennsylvania Health System, Pennsylvania State University-Milton S. Hershey Medical Center, and Geisinger Health System. In addition, the educational component included CT technologists and radiologists at 20 separate CT scan facilities.

The software utilized to extract the dose data, eXposure^{TM}, was developed by Radimetrics, Inc. and personnel from that company were responsible for building and installing virtual servers at each of the sites as well as the American College of Radiology. Radimetrics, Inc. was subsequently acquired by Bayer HealthCare in November, 2012.

16(B) Did the research project result in commercial development of any research products?

Yes_____ No_____X_____

If yes, please describe commercial development activities that resulted from the research project:

16(C) Did the research lead to new involvement with the community?

Yes_____ No____X_____

If yes, please describe involvement with community groups that resulted from the research project:

17. Progress in Achieving Research Goals, Objectives and Aims.

List the project goals, objectives and specific aims (as contained in the grant agreement). Summarize the progress made in achieving these goals, objectives and aims for the period that the project was funded (i.e., from project start date through end date). Indicate whether or not each goal/objective/aim was achieved; if something was not achieved, note the reasons

why. Describe the methods used. If changes were made to the research goals/objectives/aims, methods, design or timeline since the original grant application was submitted, please describe the changes. Provide detailed results of the project. Include evidence of the data that was generated and analyzed, and provide tables, graphs, and figures of the data. List published abstracts, poster presentations and scientific meeting presentations at the end of the summary of progress; peer-reviewed publications should be listed under item 20.

This response should be a DETAILED report of the methods and findings. It is not sufficient to state that the work was completed. Insufficient information may result in an unfavorable performance review, which may jeopardize future funding. If research findings are pending publication you must still include enough detail for the expert peer reviewers to evaluate the progress during the course of the project.

Health research grants funded under the Tobacco Settlement Act will be evaluated via a performance review by an expert panel of researchers and clinicians who will assess project work using this Final Progress Report, all project Annual Reports and the project's strategic plan. After the final performance review of each project is complete, approximately 12-16 months after the end of the grant, this Final Progress Report, as well as the Final Performance Review Report containing the comments of the expert review panel, and the grantee's written response to the Final Performance Review Report, will be posted on the CURE Web site.

There is no limit to the length of your response. Responses must be single-spaced below, no smaller than 12-point type. If you cut and paste text from a publication, be sure symbols print properly, e.g., the Greek symbol for alpha (α) and beta (ß) should not print as boxes (□) and include the appropriate citation(s). DO NOT DELETE THESE INSTRUCTIONS.

Objective:

Four ACRIN Pennsylvania Network (ACRIN PA) sites, which include community hospitals and outpatient clinics, performing CT in Pennsylvania will be identified to participate in the project. CT scan dose information will be collected from participating sites over a 6 month observational period. Sites will then be randomized to one of several dose reduction strategies and interventions will be implemented accordingly. Following the intervention, CT dose rate data will be collected for another year to determine how effective the intervention was in lowering dose.

Performance measures:

Given the importance of this issue and the high level of public interest in this topic, we intend to publish the results of this project in both scientific and non-scientific publications. This project will also provide quantitative evidence of the level of dose reduction achieved by participating sites which is expected to be significant. The data resulting from the comparison

of different dose reduction interventions will also be particularly useful to imaging practices around the state looking to incorporate best practices.

Specific Aim 1:
To survey the distribution of radiation doses received at CT at select practice sites across Pennsylvania.

Study Design

In our study design, we hypothesized that there would be great variation in the doses received by patients for the same types of CT studies, up to 10-fold for specific types of examinations, within and across sites. While some of the variation would be related to differences in CT technology across the different sites, the contribution of which is generally not controllable by the physician and technologist users, we hypothesized that the majority of the variation would be related to factors under the control of the users. These factors included physician (primarily radiologist) choices concerning desired image quality, number of acquisition phases per study, and choice to utilize dose reduction technologies available, as well as factors under the control of the scanning CT technologist, such as overscanning (including a greater portion of the body in the scan than is needed) and changing scan parameters at the time of the study in an effort to improve image quality.

Project Initiation

During the first year of funding, four sites from the previously-established ACRIN Pennsylvania (PA) Network were approached and agreed to participate in the study, assenting to the installation of software, eXposure™, developed by Radimetrics, Inc. to extract dose data. The study protocol was developed and circulated to staff at the potential sites: University of Pennsylvania Health System (UPHS), University of Pittsburgh Medical Center (UPMC), Geisinger Health System, and Pennsylvania State University – Milton S. Hershey Medical Center (PSU-Hershey).

The design called for dose information from CT examinations performed at facilities associated with the four ACRIN PA Network sites to be collected for an initial six-month period and analyzed overall for the state as well as in subgroups related to geography, practice size and type, generation of scanner, and for individual practices. As noted above, sites would then be randomized to one of several dose reduction strategies and interventions would be implemented accordingly. Following the intervention, CT dose rate data will be collected for another year to determine how effective the intervention was in lowering dose. The protocol, schema, and appendices may be viewed here: http://www.acrin.org/Portals/0/Protocols/4007/Protocol-ACRIN-PA-4007_AdminUp_ForOnline_17Dec2012.pdf.

While the study was exempted from approval by the Institutional Review Board (IRB) of the American College of Radiology, the IRBs of the University of Pennsylvania Health System and University of Pittsburgh Medical Center determined, for separate reasons, that while the

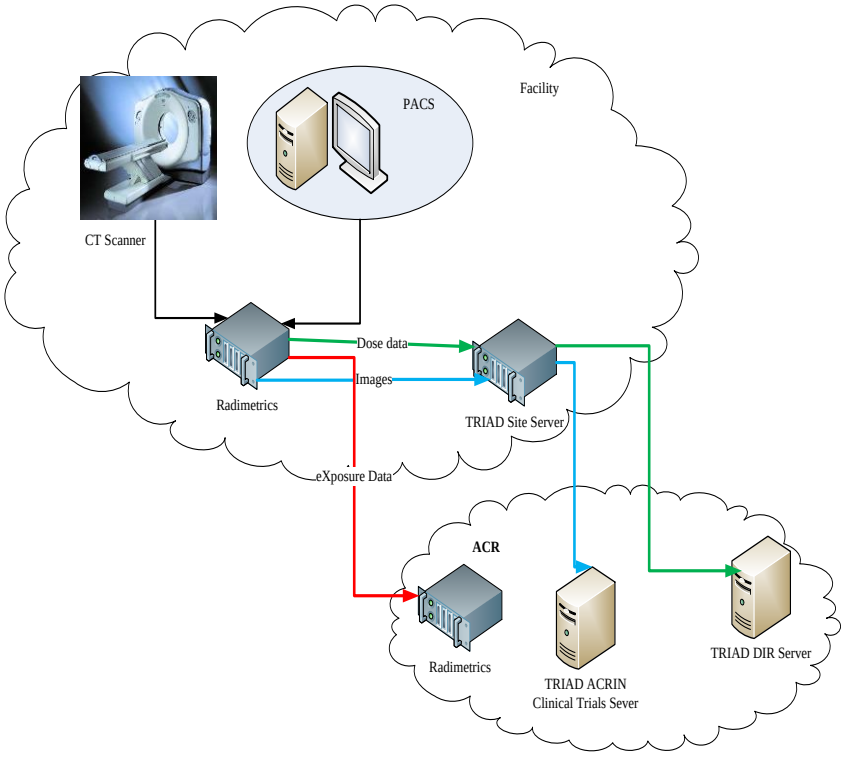
anonymized data collection could possibly be exempted, the educational component (dose reduction strategies) would require consent of the technologists involved. By late 2012, the Principal Investigator had visited and surveyed the sites and collected consents; sites were registered with the ACR dose index registry.

In November, 2012, Bayer Corporation acquired Radimetrics, Inc. during study team negotiations with the company to customize the eXposure software platform for the study. The management of Radimetrics, with whom the study leadership had negotiated (including the CEO, who had committed the company's resources to this project) was terminated shortly after the takeover. Bayer required the study team to begin negotiations again, and to have new contracts drawn up and approved by each institution and ACRIN. While Geisinger, Pennsylvania State-Hershey (PSU-Hershey) and University of Pennsylvania Health System (UPHS) eventually completed their contracts, the University of Pittsburgh was unable to come to mutually agreeable terms with Bayer and therefore they were not able to participate, leaving only three institutions to participate. Penn Community Radiology was later added as an alternative site. The additional negotiations and limited system development resources at Radimetrics/Bayer delayed the project substantially.

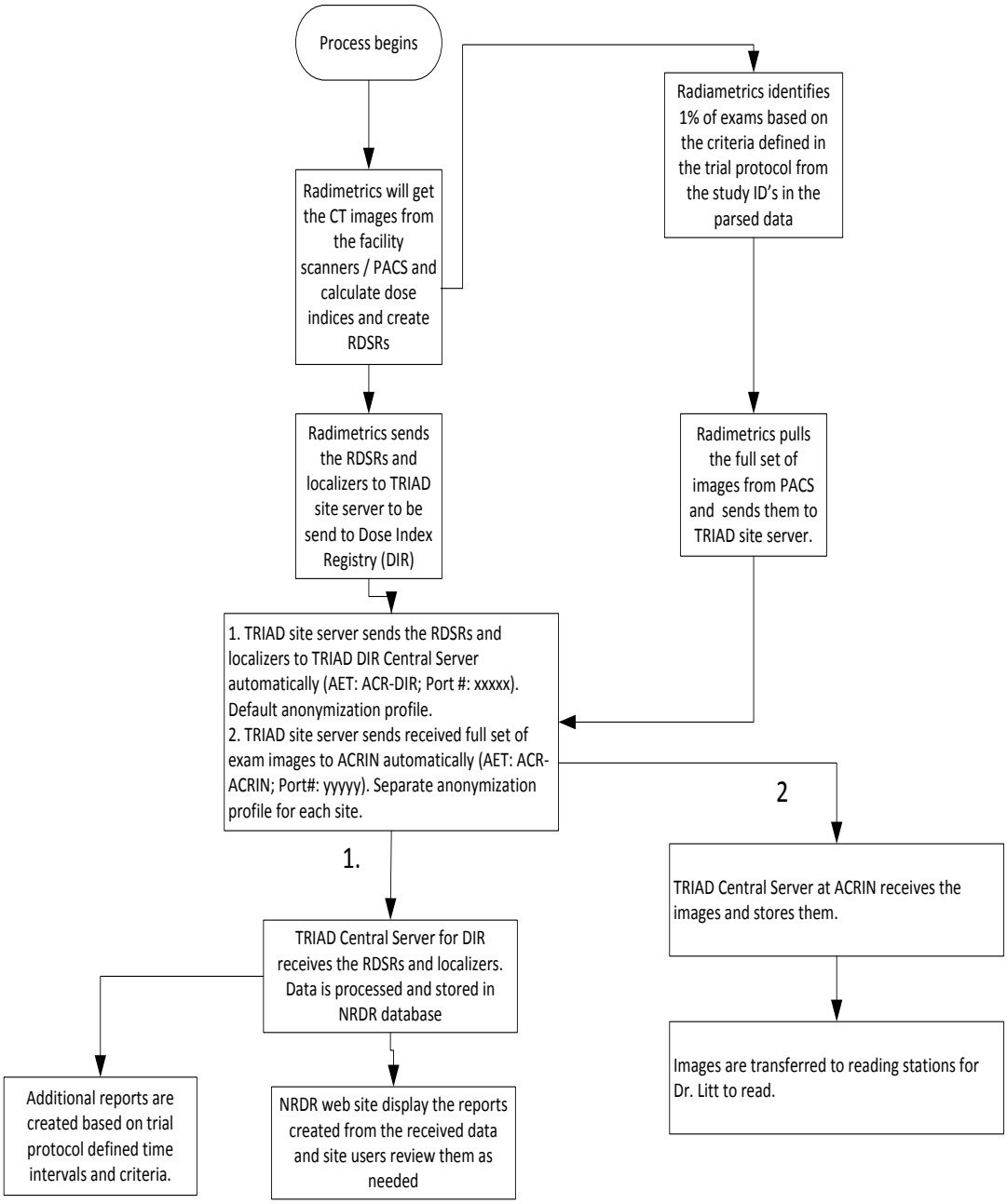
CT scan dose data collection began at UPHS, Penn Presbyterian Hospital and Pennsylvania Hospital in April, 2014 and from Penn Community Radiology practices in May, 2014. Geisinger and PSU-Hershey data collection commenced in August, 2014. These delays forced a timeline change to the project with baseline data collection continuing through November, interventions occurring in December and January and follow up data collection continuing into early 2015 with support from the ACR as Commonwealth funding expired.

In addition to the dose data to be collected, we had initially planned to collect a small random sampling of images along with dose data for all of the scans and considerable effort was expended developing and testing the interface between eXposure and TRIAD (ACR's web-based image transmission system) as seen in the proposed data flow and illustration below. However, given the contracting delays, we chose to forego this facet of the study as we did not wish to further delay data collection while the necessary programming changes to eXposure were undertaken to allow image transfer.

Proposed Overview



Proposed Data Flow



Data Collection

Dose data from 84,313 exams were obtained during 2014 and an additional 104,352 exams through May 26, 2015. The following 23 sites and 49 scanners (Table 1) were included in the data collection (note some scanners at PSUMC, HUP, PCAM, and PPMC were replaced during the study, thus not all scanners were active at the same time).

Health System	Site	Manufac-turer	Scanner	Slices /Tech	Radiology group	Tech group	Mean household income	Hospital/Outpatient	Envir-onment
PSUMC	ECCT	Siemens	Sensation40	40	PSUMC	PSUMC	45098	Outpatient	Rural
	PSUMC	Siemens	Sensation40	40	PSUMC	PSUMC	45098	Hospital	Rural
	PSUMC	Siemens	Definition Flash	128 dual	PSUMC	PSUMC	45098	Hospital	Rural
	PSUMC	Siemens	Definition Flash	128 dual	PSUMC	PSUMC	45098	Hospital	Rural
	PSUMC	Siemens	Definition Flash	128 dual	PSUMC	PSUMC	45098	Hospital	Rural
	PSUMC	Siemens	DefinitionDS	64 dual	PSUMC	PSUMC	45098	Hospital	Rural
	PSUMC	Siemens	Sensation16	16	PSUMC	PSUMC	45098	Hospital	Rural
Penn	HUP	Siemens	Definition Edge	128	HUP	HUP	21801	Hospital	Urban
	HUP	Siemens	Definition Flash	128 dual	HUP	HUP	21801	Hospital	Urban
	HUP	Siemens	DefinitionDS	64 dual	HUP	HUP	21801	Hospital	Urban
	HUP	Siemens	AS+	128	HUP	HUP	21801	Hospital	Urban
	HUP	Siemens	Sensation64	64	HUP	HUP	21801	Hospital	Urban
	HUP	Siemens	Sensation16	16	HUP	HUP	21801	Hospital	Urban
	PCAM	Siemens	Force	192 dual	HUP	HUP	21801	Outpatient	Urban
	PCAM	Siemens	AS-	40	HUP	HUP	21801	Outpatient	Urban
	PCAM	Siemens	AS+	128	HUP	HUP	21801	Outpatient	Urban
	PCAM	Siemens	Sensation Cardiac	16	HUP	HUP	21801	Outpatient	Urban
	Radnor	Siemens	Sensation10	10	HUP	Radnor	103020	Outpatient	Suburban
	Radnor	Siemens	AS+	128	HUP	Radnor	103020	Outpatient	Suburban
	PPMC	Siemens	VolumeZoom	4	HUP	PPMC	21801	Hospital	Urban
	PPMC	Siemens	Sensation64	64	HUP	PPMC	21801	Hospital	Urban
	PPMC	GE	Revolution	256	HUP	PPMC	21801	Hospital	Urban
	PPMC	GE	RevolutionGSI	64 HD	HUP	PPMC	21801	Hospital	Urban
	VF	GE	VCT	64	HUP	VF	132237	Outpatient	Suburban
	PAH	Siemens	Sensation16	16	PAH	PAH	42194	Hospital	Urban
	PAH	Siemens	Definition Flash	128 dual	PAH	PAH	42194	Hospital	Urban
	PAH	Siemens	Sensation4	4	PAH	PAH	42194	Hospital	Urban
Community	CCH	GE	CTi	1	Community	CCH	84807	Hospital	Suburban
	CCH	Siemens	Sensation16	16	Community	CCH	84807	Hospital	Suburban
	CCH	Siemens	Sensation64	64	Community	CCH	84807	Hospital	Suburban
	Fernhill	Siemens	Sensation16	16	Community	CCH	84807	Outpatient	Suburban
	Oaklands	Siemens	EmotionDuo	2	Community	CCH	89659	Outpatient	Suburban
	Kennett Square	Siemens	Emotion6	6	Community	CCH	90631	Outpatient	Suburban
	Yardley	Siemens	Sensation40	40	Community	Yardley	87627	Outpatient	Suburban
	Oaklands	Siemens	Sensation16	16	Community	CCH	89659	Outpatient	Suburban
Geisinger	Susquehanna	Siemens	Sensation64	64	Geisinger	Susquehanna	47136	Outpatient	Rural
	Bloomsburg	GE	VCT	64	Geisinger	Bloomsburg	45206	Hospital	Rural
	GMC	GE	VCT	64	Geisinger	GMC	48561	Hospital	Rural
	GMC	Toshiba	Aquilion	64	Geisinger	GMC	48561	Hospital	Rural
	GMC	Toshiba	Aquilion	64	Geisinger	GMC	48561	Hospital	Rural
	Grays Woods	GE	VCT	64	Geisinger	Grays Woods	85023	Outpatient	Rural
	Woodbine	Toshiba	Aquilion	64	Geisinger	Woodbine	48561	Outpatient	Rural
	CMC	Philips	Brilliance64	64	Geisinger	CMC	31935	Hospital	Urban
	CMC	Philips	Brilliance64	64	Geisinger	CMC	31935	Hospital	Urban
	Shamokin	Toshiba	Aquilion	32	Geisinger	Shamokin	35675	Hospital	Rural
	GWV	GE	Lightspeed16	16	Geisinger	GWV	35770	Hospital	Urban
	GWV	GE	VCT	64	Geisinger	GWV	35770	Hospital	Urban
	GWV	Toshiba	Aquilion	32	Geisinger	GWV	35770	Hospital	Urban
	Mobile	GE	Lightspeed16	16	Geisinger	Mobile	49189	Outpatient	Rural

Table 1: List of Sites and Scanners included in ACRIN PA 4007 data collection. PSUMC = Pennsylvania State University- Hershey Medical Center, ECCT = Hershey East Campus CT, HUP = Hospital of the University of Pennsylvania - Philadelphia, PCAM = Penn Perelman Center for Advanced Medicine - Philadelphia, PPMC = Penn Presbyterian Medical Center - Philadelphia, VF = Valley Forge, PAH = Pennsylvania Hospital - Philadelphia. Community = University of Pennsylvania Community Radiology Practice, CCH = Chester County Hospital, GMC = Geisinger Medical Center - Danville, CMC = Community Medical Center - Scranton, GWV = Geisinger Wyoming Valley - Wilkes-Barre

Data Evaluation

A. Overall Dose Comparison

1. Site Level Comparison

We compared doses overall among the 4 sites using several different ways to express radiation dose. CTDIvol (volumetric dose index) is a value reported by the CT scanner that is based upon the technical parameters of the scan (kVp, mAs, pitch) without regard to the body part being imaged, except for dividing scans into head and other body parts. DLP (dose length product) is CTDIvol multiplied by scan length, and thus takes into account differences in scan length. SSDE (size specific dose estimate) adjusts the CTDIvol based upon patient size, and may provide a better way to compare across different sites if the sites have larger or smaller patients than average. However, only newer scanners provide the information needed to calculate SSDE; approximately 60% of Penn, 40% of Penn Community, 75% of PSU-Hershey, and 75% of Geisinger scans were acquired on machines that provide SSDE data. Effective dose (in mSv) reflects the biological effect of a radiation dose on a patient and takes into account the radiation sensitivity of the tissues being imaged.

(a) Data acquired in 2014

Site	Eff Dose (mSv)	#	DLP body (mGy-cm)	#	CTDIvol body (mGy)	#	CTDIvol head (mGy)	#	SSDE (mGy)	#
Penn	6.7	24814	535.3	18029	11.4	18029	44.7	7865	16.4	14718
Penn Community	8.5	9735	672.8	6873	13.1	6873	44.5	3155	19.4	3647
PSU-Hershey	9.2	11672	724.1	9058	14.2	9058	47.3	3485	20.5	8820
Geisinger	13.9	33780	1117.9	25729	19.6	25729	48.7	12612	32.7	25172

(b) Data acquired through May 26, 2015

Site	Eff Dose (mSv)	#	DLP body (mGy-cm)	#	CTDIvol body (mGy)	#	CTDIvol head (mGy)	#	SSDE (mGy)	#
Penn	6.6	46981	521.2	34972	10.7	34972	43.2	13677	15.2	31497
Penn Community	8.7	13425	673.3	9658	13.0	9658	43.9	4188	19.1	6391
PSU-Hershey	9.2	28587	725.1	21992	14.2	21992	48.2	8771	20.3	21384
Geisinger	13.8	73745	1121.8	55677	19.6	55677	48.2	51451	31.6	54088

Table 2: Mean of radiation dose at each of the 4 health systems, expressed in terms of Effective Dose, DLP body, CTDIvol body and head, and SSDE. (a) Data acquired in 2014 only (b) Data acquired through May 26, 2015. See text above.

As can be seen in Table 2, there were considerable differences in effective dose between systems, with the highest dose system value over twice as high as the lowest (13.9 mSv vs. 6.7 mSv, p=0). Note that only slight differences are present in CTDIvol head, with only a 10% difference between the highest and lowest dose system. Evaluation of the remaining non-head scans shows persistence of the differences among the sites, although to a slightly lesser degree (e.g. SSDE 32.7 mGy vs. 16.4 mGy) suggesting that Geisinger does have slightly larger patients than Penn but that the vast majority of the dose difference is related to factors other than patient size.

2. Manufacturer Level Comparisons

Manufacturer	Eff Dose (mSv)	#	DLP body (mGy-cm)	#	CTDIvol body (mGy)	#	CTDIvol head (mGy)	#	SSDE (mGy)	#
Siemens	7.9	46336	628.4	34300	12.4	34300	45.3	14028	18	27660
Philips	9.6	7518	729.9	5243	14.6	5243	58	3283	23.1	5238
GE	12.9	11284	963.6	9755	16.9	9755	41.4	2928	26.4	9314
Toshiba	16.6	13725	1412.5	9812	24.9	9812	46.4	5826	44.6	9662

Table 3: Mean of radiation dose by scanner manufacturer, expressed as Effective dose, DLP body, CTDIvol body and head, and SSDE

As seen in Table 3, there was considerable variation in dose among the different scanner manufacturers, again with a greater than 2-fold variation between highest and lowest average dose (16.6 mSv for Toshiba vs. 7.9 mSv for Siemens). As with site variability, the head doses are much closer to one another (with the exception of Philips, which is an outlier at higher doses) – note that the American College of Radiology suggests that head CT dose should be <60 mGy so all sites and manufacturers meet this guideline. However, in this case, using SSDE reveals an even greater difference between high and low dose manufacturers (44.6 mGy vs. 18 mGy, a 2.5x difference), suggesting that average patient size plays no role in the difference between these two manufacturers.

One difficulty with determining the relative contributions of equipment manufacturer vs. factors under the sites' control is that there was an asymmetric distribution of scanners across the different sites. For example, the only two Philips scanners were at a single Geisinger site, all Toshiba and most of the GE scanners were at Geisinger sites, while Hershey, Penn Community Radiology and Penn primarily used Siemens scanners. Given this, it may be difficult to say whether higher doses at Geisinger were related to the manufacturer or radiologist protocol or technologist scanning choices. However, evaluation of the range of mean doses across Geisinger sites, and those at two specific sites, may provide some insight.

Figure 1 shows the overall mean doses across the different Geisinger sites during the baseline data collection period. Note that there is considerable variation across sites, with the highest mean dose site (GMC Woodbine – 24.1 mSv) at 3.5x higher mean dose than the lowest mean dose site (Bloomsburg Hospital – 6.9 mSv). Of interest however is that Bloomsburg Hospital uses a GE VCT scanner, yet has a mean dose much lower than other VCT sites (6.9 mSv vs. 13.9 mSv), and Susquehanna Valley Imaging uses a Siemens Sensation64 scanner, yet has a much higher mean dose than this scanner when used at sites at Penn, Penn Community Radiology, and Hershey (14.8 mSv vs. 7.7 mSv). Similarly, GMC Woodbine, with a Toshiba Aquilion scanner, had much higher overall mean dose than other sites using this scanner, despite all of those sites also being within Geisinger (24.1 mSv vs. 16.2 mSv). These outliers suggest that institutional factors, such as protocol choices and technologist performance, may have a larger impact upon doses than scanner manufacturer or model. However, these three sites had relatively smaller volumes of scans than other sites within Geisinger, so small differences may be exaggerated.

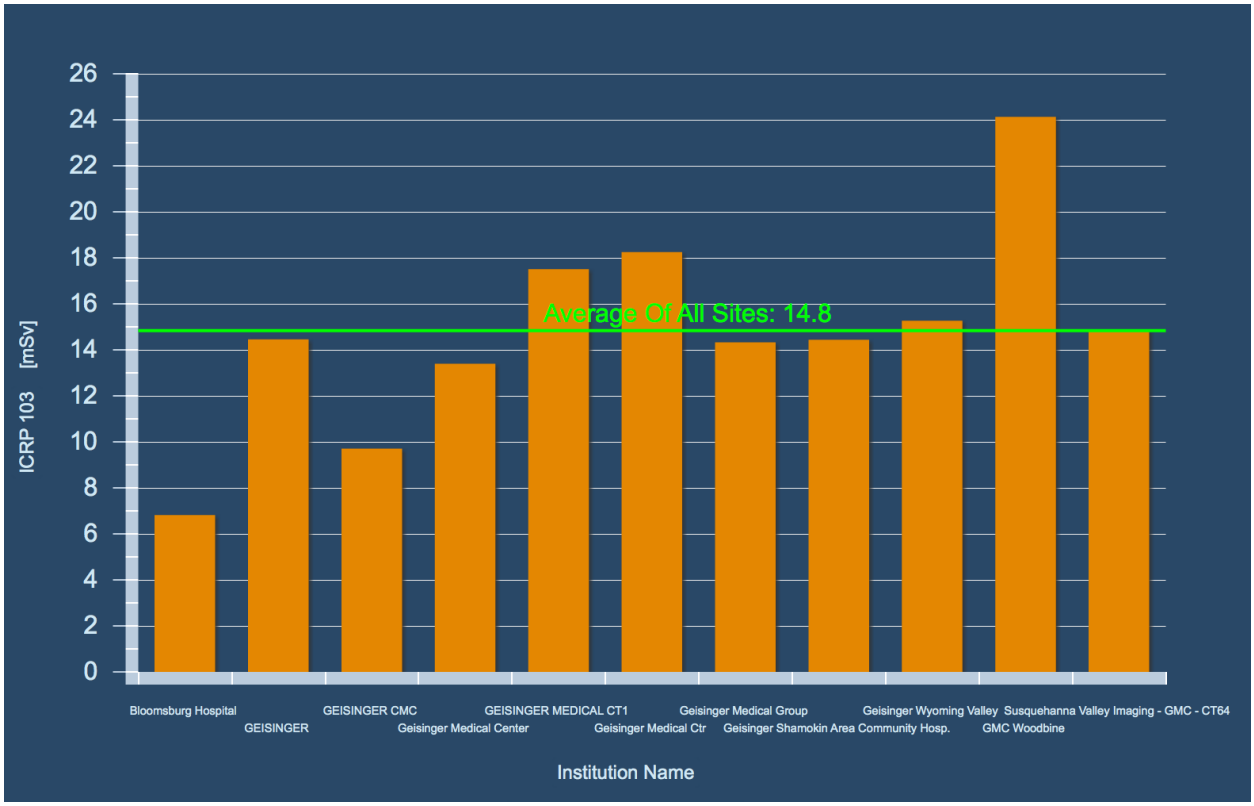


Figure 1: Overall mean doses across different Geisinger Health System sites during the baseline period. Note considerable variability in overall mean dose within this one health systems despite centralized protocoling. Of particular interest are several outliers – GMC Woodbine with higher overall mean doses and Bloomsburg Hospital with overall lower mean doses compared to other sites using the same Toshiba and GE scanners, and Susquehanna Valley Imaging, with average overall mean dose for Geisinger, but higher doses than Penn and Hershey sites using the same Siemens scanner. This suggests that institutional factors are more important than scanner manufacturer in determining doses.

3. Hospital-Based Outpatient Imaging Centers

Setting	Eff Dose (mSv)	#	DLP body (mGy-cm)	#	CTDIvol body (mGy)	#	CTDIvol head (mGy)	#	SSDE (mGy)	#
Hospital	10.7	57621	884.6	41907	16.6	41907	46.3	20959	27.4	36716
Outpatient	9.3	15007	682.8	12459	12.3	12459	38	2869	17.7	10318

Table 4: Mean of radiation dose by setting (hospital based vs. outpatient only), expressed as Effective dose, DLP body, CTDIvol body and head, and SSDE

Table 4 demonstrates systematically higher doses for scans performed in the hospital setting vs. outpatient imaging centers. Although the difference in effective dose was only 15%, there were greater differences in CTDIvol for both head and body scans, and particularly for

SSDE, which showed a 55% increase for hospital based imaging doses. This suggests again that patient size for hospital vs. outpatient scanning did not play a role in the higher doses and that the differences were related to protocol choices or inherent differences in the equipment. Note that the magnitude of the difference between inpatient and outpatient doses may be underestimated as many outpatients may have been scanned on hospital based machines.

4. Analysis by Level of CT Technology

Technology	Eff Dose (mSv)	#	DLP body (mGy -cm)	#	CTDI vol body (mGy)	#	CTDI vol head (mGy)	#	SSDE (mGy)	#
1-16 slice	10.1	5983	768.6	4596	13.9	4596	48.3	1753	21.2	3103
32-64 slice	11.9	47606	966.3	35126	17.7	35126	47.7	17215	29.6	31944
>64 slice, dual source, HD	7.4	25014	590.3	18601	12.3	18601	45.2	7890	17.9	15862

Table 5: Mean of radiation dose by level of technology (1-16 slice CT, 32-64 slice, and >64 slice/dual source/HD CT), expressed as Effective dose, DLP body, CTDIvol body and head, and SSDE

We explored the role of level of technology on dose by dividing the scans into those performed on 1-16 slice machines, 32-64 slice machines, and machines of >64 slice or those using dual source or HD technology (Table 5). These categories were chosen as they reflect >10 year old technology (1-16 slice), 5-10 year old technology (32-64 slice) and <5 year old technology (with the exception of the Definition DS, which is a 64 slice dual source scanner from 2007). Re-assigning the DefinitionDS to the 32-64 slice category did not change the average dose in that category (11.9 mSv) but did reduce the dose in the "new technology" category from 7.4 mSv to 6.9 mSv. The analysis revealed again that head CT doses did not vary much across different technology levels. There was some reduction in effective dose in the use of newer technology compared to 1-16 slice or 32-64 slice, however the differences became more pronounced when looking at CTDIvol body (31% reduction from 32-64 slice to newer technology) and SSDE (40% reduction from 32-64 slice to newer technology). The greater dose reduction as measured by SSDE suggests that larger patients were scanned on the newer vs. older scanners, which would make sense as the newer scanners generally have higher table capacities than older. Therefore, the expected benefits of using newer technology would be even greater when applied to patients of equivalent size. Another factor suggesting the benefit of newer technology for dose reduction is that some types of scans traditionally felt to be high dose (e.g. coronary CT and gated CT angiography) were likely preferentially performed using the newer technology scanners so that the dose reduction would be even greater if we compared a similar distribution of the types of exams between the scanner generations. However, as the vast majority of newer technology scanners analyzed in this study were manufactured by Siemens (and thus also at Hershey and Penn), we can't entirely separate the effects of manufacturer and site from the effects of newer technology.

5. Other Analyses

We had planned to do an analysis by patient socioeconomic status, using mean household income for the zip code in which the CT facility was located as a surrogate (with the exception of two Geisinger sites which dominate their zip code, leaving very few households for analysis, for which adjacent zip codes were chosen), as well as analyzing the relationship of dose to community environment (urban vs. suburban vs. rural). Our hypothesis was that sites with patients with lower socioeconomic status would have higher dose related to factors such as: level of technology in the facility, patient average size and disease status, technologist training, etc. Table 1 shows the mean household income and environment for each site; no correlation between these factors and dose could be discerned. As the analyses above demonstrated, the effects of radiologist group and/or scanner manufacturer dominated other potential contributions to the mean dose per site.

We attempted to evaluate the relative contributions of scanner manufacturer versus factors under the radiologists' and technologists' control (protocol choices and implementation) by scanning the same phantom on machines at scanners at Geisinger, Hershey, and Penn sites during the onsite technologist education sessions described in Aim 2 results below. These scans were performed using scan protocols that were as similar as possible among the three vendors to whose scanners we had access during the educational sessions. The scans were based on the noncontrast routine chest CT protocol used at each institution, with acquisitions using the default parameters at each site, as well as acquisitions at several tube current settings using several different reconstruction kernels. Analysis of these phantom images is ongoing, but focusing on radiation dose differences between scanners for the default protocols and differences in dose between protocols that result in equivalent SNR across scanners.

B. Exam Level Comparisons

For our exam level analysis, we focused on 15 specific types of CT examinations, including many of the most commonly performed types of exams (head, chest, abdomen and pelvis CT) and several types of exams known to be associated with higher radiation doses (coronary CT, CT angiography, CT Urography, and CT guidance for procedures. The exams analyzed were:

1. Unenhanced head CT
2. Head CT for sinus evaluation
3. CT angiography of the head and neck/circle of Willis/carotid arteries
4. Routine neck CT
5. Routine chest CT
6. Chest CT for pulmonary embolism evaluation
7. High resolution chest CT
8. Chest CT for lung nodule initial evaluation and follow up
9. Routine abdominal and pelvic CT
10. CT urography
11. CT angiography of the chest, abdomen, and pelvis for aortic dissection, aneurysm, or

other aortic pathology and renal or mesenteric artery evaluation
12. Coronary CT
13. CT angiography of the abdominal aorta and iliofemoral runoff
14. CT guided interventions or biopsies
15. Cervical spine CT

Table 6 shows overall mean radiation doses for those 15 exams as well as minimum and maximum scanner mean doses, i.e. the mean dose for the exam performed on the scanner with the lowest and highest mean doses.

Exam	Mean Dose Overall	Min Mean Dose by scanner	Max Mean Dose by scanner	Overall Min Dose	Overall Max Dose
	mSv	mSv	mSv	mSv	mSv
Unenhanced head CT	2.6	1.67	4.48	0.6	9.1
Head CT for sinus evaluation	1.2	0.4	4.2	0.2	25.5
CT angiography of the head and neck/circle of Willis/carotid arteries	7.6	3.2	16.3	0.9	27.4
Routine neck CT	6.2	2.8	11.2	1.3	24.6
Cervical spine CT	6	3	12.7	0.8	31.7
Routine chest CT	7.5	3.1	15.7	0.5	37.1
Chest CT for pulmonary embolism evaluation	8.5	3.3	21.6	1.3	39.9
High resolution chest CT	16.6	4	42	2.2	93.1
Chest CT for lung nodule initial evaluation and follow up	2.3	1.1	5.3	0.8	8.9
Routine abdominal and pelvic CT	11.9	6.6	26.4	1.2	146.5
CT urography	29.5	11.3	71.9	7.2	130.7
CT angiography of the chest, abdomen, and pelvis for aortic dissection, aneurysm, or other aortic pathology and renal or mesenteric artery evaluation	21.3	7.4	43.9	1.7	101.8
CT angiography of the abdominal aorta and iliofemoral runoff	14.5	3.7	37.8	2.3	43.3
Coronary CT	12.6	2	22.1	1.4	96.2
CT guided interventions or biopsies	14.1	4.8	26.1	0.2	121.4

Table 6: Radiation doses for 15 types of CT examinations subjected to in-depth analysis in ACRIN PA 4007. Mean dose overall as well as minimum and maximum mean doses by scanner are listed.

There are some limitations to the exam level analysis as the analysis was performed based upon the scan protocol initially chosen by the technologist. If additional body parts were added during the scanning (e.g. a cervical spine CT was added to a head CT), then this additional dose would be incorrectly assigned to the scan protocol initially chosen resulting in a higher reported dose. Conversely, if the entire scan protocol was not completed (e.g. only scout/topogram images were obtained or only precontrast images were obtained from a multiphase protocol), the dose would be artificially low. Based upon review of a large number of cases, these types of errors had similar incidences among the various sites, so that between site and between scanner comparisons should not be affected. However, for some types of scans, overestimation of doses occurred much more frequently than underestimation. Note that all of the overall minimum and maximum doses listed in Table 6 were verified as reflecting the dose from a complete scan using the specified protocol without any additional scans, and therefore are accurate.

As above, we hypothesized that there would be great variation in doses (up to 10 fold) between sites for certain types of exams. As shown in Table 6 and Figure 2, there was a 2.5-fold difference in the head CT doses from the lowest to highest, ranging from an average of 1.7 millisieverts (mSv) to 4.5 mSv. As described in the paragraph above, routine head CT exams more often contained additional scanning (e.g. cervical spine) than incomplete scanning. Therefore, the mean maximum dose may be overestimated. This likely accounts for the discrepancy between tables 2-5 and table 6; tables 2-5 showed only minor differences in head CT dose among different sites, manufacturers, scanner technologies, and hospital vs. outpatient settings, while table 6 shows a nearly 3-fold difference between the scanners with the lowest and highest mean head CT doses. The $CTDI_{head}$ parameter reflects only those scans with doses determined using the head phantom calculation, which would only apply to scans of the head, even if those head scans occurred in an exam including other body parts. All other body parts have doses determined using the body phantom calculation.

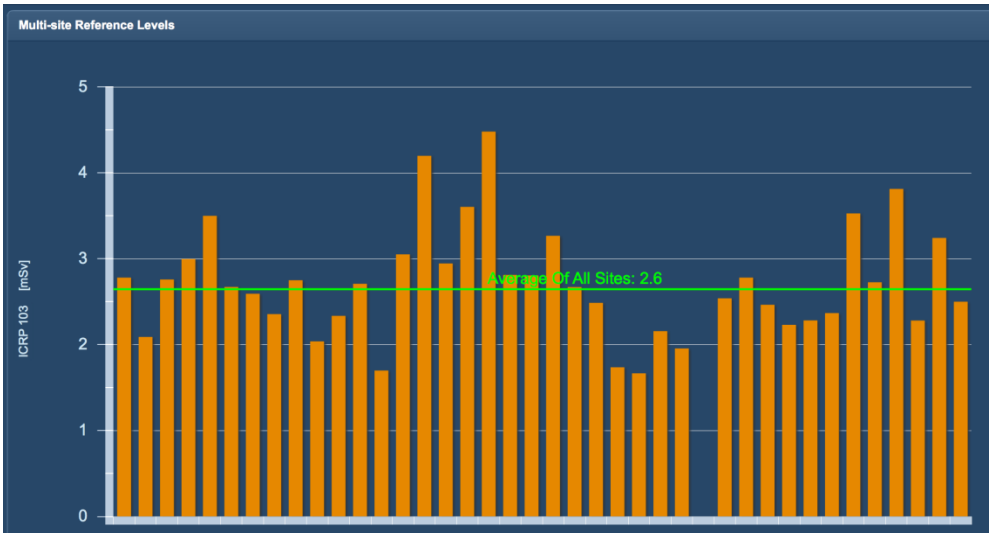


Figure 2: Average Dose of Head CT Examinations By Site Across Participating Institutions. Note 2.5x difference between institution with lowest and highest average doses, although absolute differences are relatively small.

Variability amongst participating sites was much greater for other types of scans. For example, there was a nearly 10-fold difference in average dose between the lowest and highest dose scanner (0.4 vs. 4.2 mSv) and a 100-fold difference between the sinus exam performed with the lowest and highest doses (0.2 vs. 25.5 mSv). Much of the difference between the lowest and highest mean dose scanners can be explained by the fact that some sites always include a routine head CT when performing sinus CT studies, while others do not. A similar effect was seen for high-resolution chest CT, where there was also a 10-fold difference in dose between the lowest and highest dose scanners (4 vs. 42 mSv) and a 50-fold difference between the lowest and highest dose scan. Some sites include a routine chest CT and/or prone or expiratory imaging in all of their high-resolution studies, while others add these additional acquisitions selectively. Another important protocol difference among different sites that led to dramatically different doses in HRCT and other exams was the setting of scan parameters to provide diagnostic quality images (high SNR) of the thicker slices that are the ones primarily used for diagnosis (e.g. 5 mm), while other sites increased radiation doses to give high SNR even for very thinly reconstructed slices (e.g. 1 mm) that may only be used for secondary review or workstation post-processing.

Figure 3 shows average doses by scanner/site for chest CT examinations performed for evaluation of pulmonary embolism with average doses ranging from 2 to 21.6 mSv – a more than 10 fold-difference. If we restrict the analysis to scanners/sites with more than 50 exams, excluding some outliers on the low end, the range narrows somewhat – to 5-21.6 mSv, still a greater than four-fold difference. The sites are listed in alphabetical order along the x-axis; as can be seen, sites with doses above and below the average are mostly clustered by the health system to which they belong.

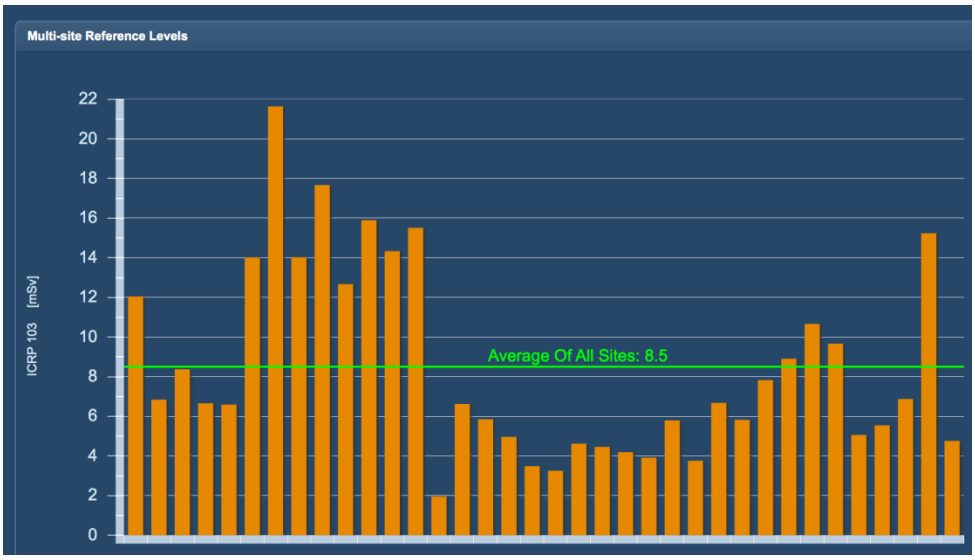


Figure 3: Variability in Average Dose for Pulmonary Embolism Chest CT exams Across Participating Sites. Note that some outliers on the low end had a small number of exams.

Similar variability was found in abdomen/pelvis CT, as seen in Figure 4, with low dose sites in the 6-8 mSv range and high dose in the 24-26 mSv range. Even greater variation was seen in CT

urogram doses, which ranged from 10 to greater than 70 mSv across sites. (Figure 5) Note that doses above 50 mSv for a single exam are in the range where there is reasonable evidence of a potential increase in the risk of cancer related to radiation exposure. Higher dose sites routinely included additional scan phases in urography protocols, while lower dose sites limited the scan volume and reduced dose dramatically for any additional phases.

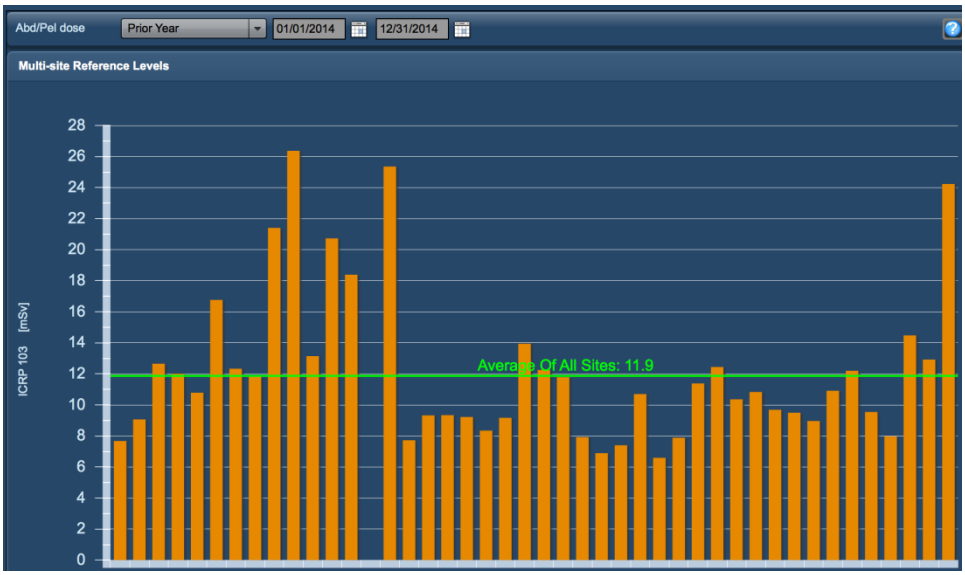


Figure 4: Variability in Abdomen/Pelvis CT dose across participating sites

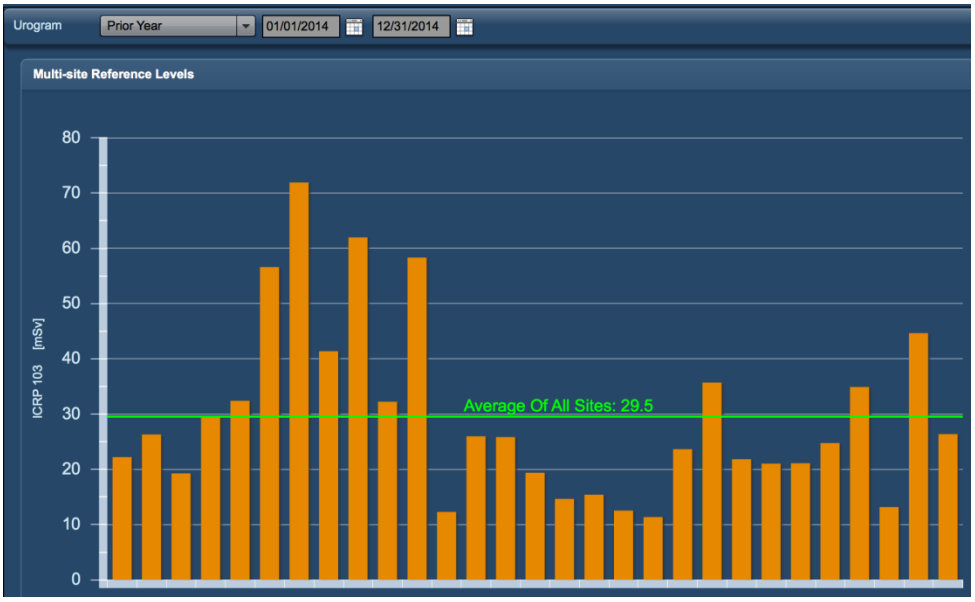


Figure 5: Variability in Doses for CT Urograms Across Participating Sites

Overall, the following protocol (radiologist) related factors were observed to contribute to differences in dose for the same exam among the various sites, with several examples:

1. Routine vs. selective use of multiphase or multi-acquisition scans
    a. HRCT – routine inclusion of full chest, prone, or expiratory scanning
    b. Sinus – routine inclusion of head CT
    c. Abdomen/Pelvic CT – routine use of pre and post contrast scans
    d. Urogram – routine inclusion of two or more delayed scans
2. Use of same imaging parameters (i.e. full dose scans) for all phases of multiphase exams
    a. CT angiography studies with full dose precontrast and delayed scans
    b. Full dose scans for localizing pulmonary arteries in PE studies
    c. Full dose scans for imaging of all passes during CT guided biopsies
3. Imaging full volume for all phases of multiphase exams
    a. Delayed imaging of the entire abdomen/pelvis in post-AAA stent cases
    b. Multiphase imaging of the entire abdomen/pelvis in multiphase liver examinations
4. Decision not to use automated dose reduction capabilities of newer CT scanners
    a. All CTA examinations performed at 120 kVp
    b. Automated tube current modulation either not turned on or inappropriately set, causing thinner patients to receive more dose than necessary
5. Presence or absence of specific scanner technology
    a. Sites that did not have prospective triggering for coronary CTA and thus performed all cases with retrospective gating, resulting in 3-5x higher doses for those cases
    b. Automated vs. manual kVp adjustment – see Figures 6 and 7 for further discussion
    c. Variations among manufacturers in implementation of automated tube current adjustment
    d. Presence or absence of iterative reconstruction, and its use if present – this only affected a small number of sites with access to this technology

Technologist related factors were also noted to contribute to dose variability, however these were not systematic differences between sites and contributed more to lesser degrees of within site variation:

1. Overscanning
    a. PE studies – routine overscanning to include much of the abdomen
    b. Coronary CTA – routine inclusion of the entire thoracic aorta
2. Patient positioning
    a. Patients not centered in gantry

These factors were included in the on-site technologist education programs described in the results of Aim 2.

Specific Aim 2:
To evaluate the impact of various strategies for providing dose reduction education to sites performing CT in Pennsylvania.

Intervention Strategies

The second phase of the study required implementation of different educational strategies. Separate radiologist and technologist groups were randomized to a particular intervention as delineated here:

Technologist Group 1 Cohort: required viewing of web-based manufacturer specific educational materials concerning radiation dose reduction methods available for the particular site's scanners. An example of the Toshiba-based material required for technologist viewing is Toshiba's *Sure Exposure Low Dose Image Quality*. Technologists indicated their "attendance" via a web-based survey link.

Technologist Group 2 Cohort: on-site training including presentation of recommended protocols for most common CT exams. An on-site education session was presented at each facility.

These presentations reviewed dose data for each individual site and compared this to other sites in the trial. Comparisons across scanners at a given site were also demonstrated where appropriate. We then presented methods that technologists could use to optimize scan quality, while minimizing dose, for various types of scans. Examples of overscanning and suboptimal patient positioning from that site were presented, with discussion of how these things influenced the dose for that patient and demonstration of lower doses for properly scanned cases. We reviewed scan protocols that had particularly high doses at each site, and determined whether these high doses were the result of protocol choices or issues with technologist implementation. The majority were determined to be related to radiologist protocol choices, however there were some cases in which technologists had misinterpreted radiologist protocol instructions, leading to systematic overdosing.

We explained the theory and operation of the various dose reduction technologies built into the scanners in use at each facility, and how the technologists could perform the scans to take best advantage of these technologies. For example, proper patient positioning (arms out of field of view for chest scans and patient centered in gantry) allows automated tube current modulation algorithms to provide maximal dose reduction. Finally, we answered any technologist questions about their scanners and implementation of dose reduction techniques, and created a list of action items (e.g. review of specific protocols to make sure that they were the same across scanners, protocol questions for discussions with their radiologists) for follow-up. After that, one-on-one sessions were conducted with the technologists at each scanner, reviewing recent cases as well as scan protocols and implementation of dose reduction technology for that scanner.

Radiologist Group 1: Radiation dose report as provided by ACR's national dose registry
Radiologist Group 2: Monthly radiation report with more extensive analysis

ShortNameReport	*Body Part*	*DIR Standing*	*N*	*25th %'ile*	*Median*	*75th %'ile*
CT ABDOMEN ANGIO W IVCON	**ABDOMEN**	25th-75th %'ile	6	15	15	17
CT ABDOMEN PELVIS ANGIO	**ABDOMEN PELVIS**	25th-75th %'ile	70	15	21	23
CT ABDOMEN PELVIS W IVCON	**ABDOMEN PELVIS**	Above 75th %'ile	3	15	21	27
CT ABDOMEN W IVCON	**ABDOMEN**	Above 75th %'ile	10	10	22	23
CT ABDOMEN WO IVCON	**ABDOMEN**	25th-75th %'ile	34	14	19	21
CT C SPINE W IVCON	**CERVICAL SPINE**	NA				
CT CHEST ABDOMEN PELVIS ANGIO	**CHEST ABDOMEN PELVIS**	Above 75th %'ile	2	64	67	70
CT CHEST ABDOMEN PELVIS W IVCON	**CHEST ABDOMEN PELVIS**	Above 75th %'ile	35	12	22	28
CT CHEST ABDOMEN PELVIS WO IVCON	**CHEST ABDOMEN PELVIS**	Above 75th %'ile	1	26	26	26
CT CHEST HIGH RESOLUTION WO IVCON	**CHEST**	Above 75th %'ile	1	26	26	26
CT CHEST LUNG BIOPSY GUIDANCE	**CHEST**	25th-75th %'ile	4299	36	42	63
CT CHEST W IVCON	**CHEST**	25th-75th %'ile	307	10	14	20
CT CHEST WO IVCON	**CHEST**	25th-75th %'ile	429	10	16	22
CT HEAD ANGIO W IVCON	**HEAD**	NA				
CT HEAD BRAIN W IVCON	**HEAD**	NA				
CT HEAD BRAIN WO IVCON	**HEAD**	NA				
CT HEAD PARANASAL SINUSES WO IVCON	**HEAD**	NA				
CT NECK W IVCON	**NECK**	NA				
CT NECK WO IVCON	**NECK**	NA				
CT PELVIS W IVCON	**PELVIS**	25th-75th %'ile	11	10	15	18
CT PELVIS WO IVCON	**PELVIS**	25th-75th %'ile	10	22	26	30

Table 7: Excerpt from the ACR national dose registry report provided to one of the sites. The report includes the number of each type of studies performed as well as the doses for each site corresponding to the 25th percentile, median and 75th percentiles. The median dose is color coded to denote whether that sites median dose is below the 25th percentile nationally (blue), within the 25-75th percentile range (yellow) or above the 75th percentile nationally (orange). This site had median doses above the 75th percentile nationally for half of the exams shown, and did not have any median doses below the 25th percentile nationally. Note the large number of cases listed as "CT chest lung biopsy guidance," which clearly does not correspond to the actual number of cases of this type performed. One of the downsides of the ACR dose registry is that the accuracy of data analysis is dependent upon accurate coding of exam types by the sites.

Our reports to the sites included more in-depth analysis. Figures 5-7 are excerpted from a report to one of the sites. Figure 6a demonstrates CT urogram doses from different scanners at PSUMC for the baseline period, showing an average dose of 24.7 mSv, but with one scanner having a mean dose of 36 mSv. After the on-site intervention, Figure 6b shows that total mean dose

dropped to 20.7 mSv, with a decrease in scanner CT3 to 22 mSv related to a change in protocol after the intervention.

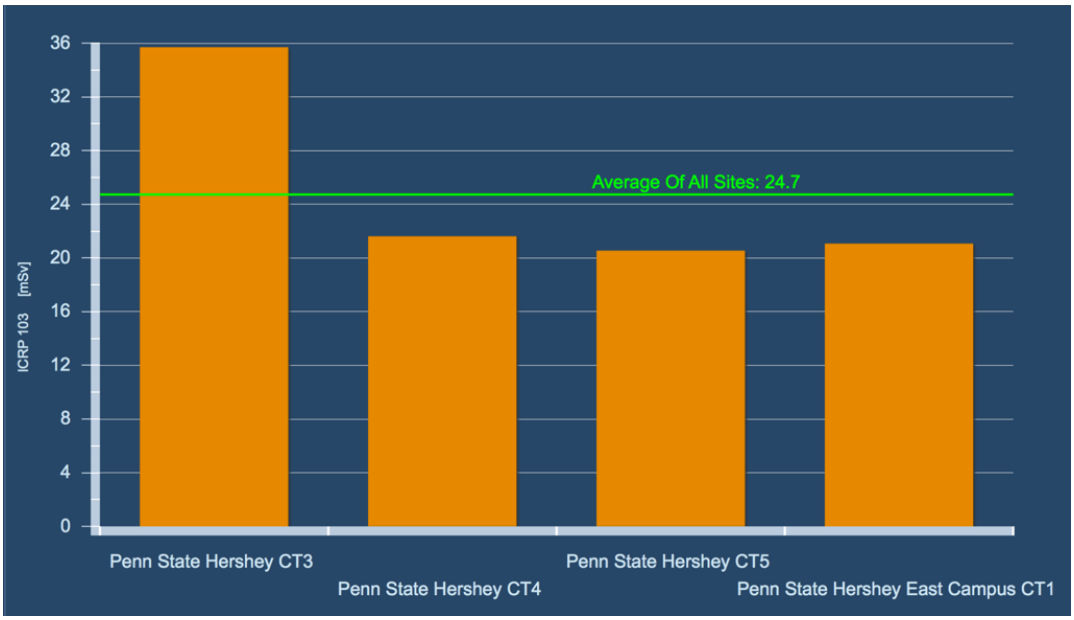


Figure 6(a)

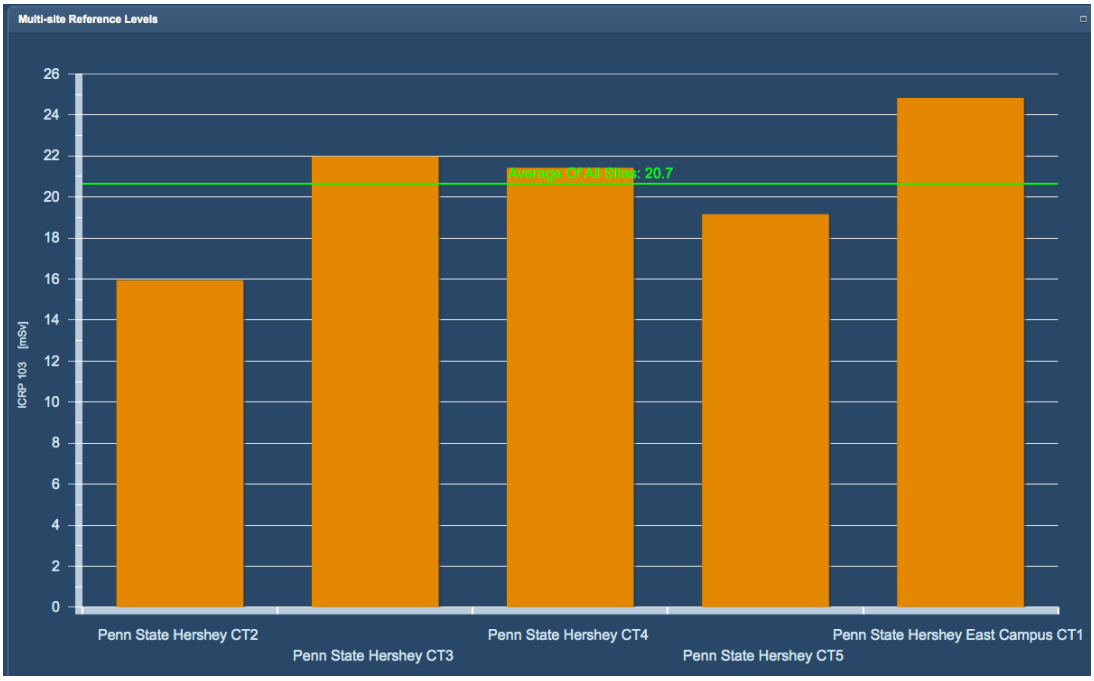
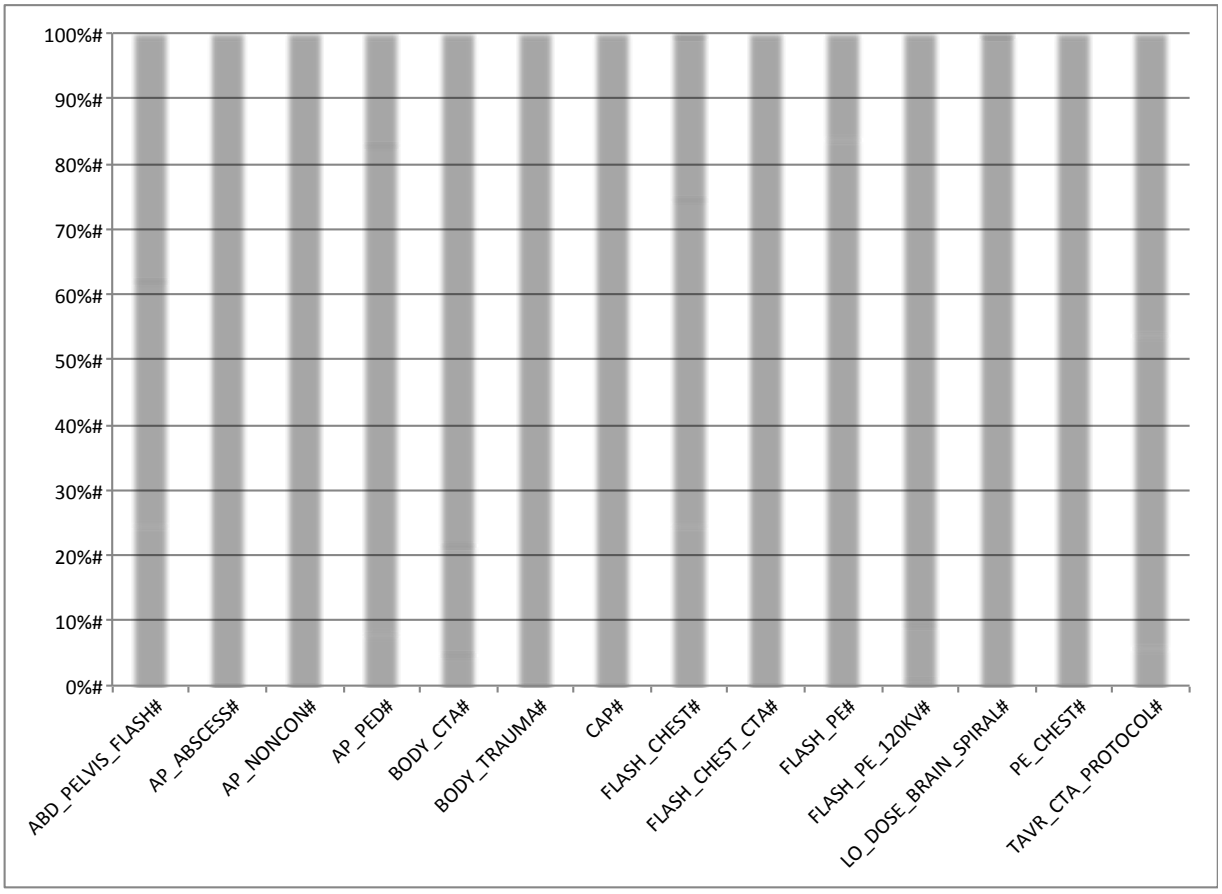


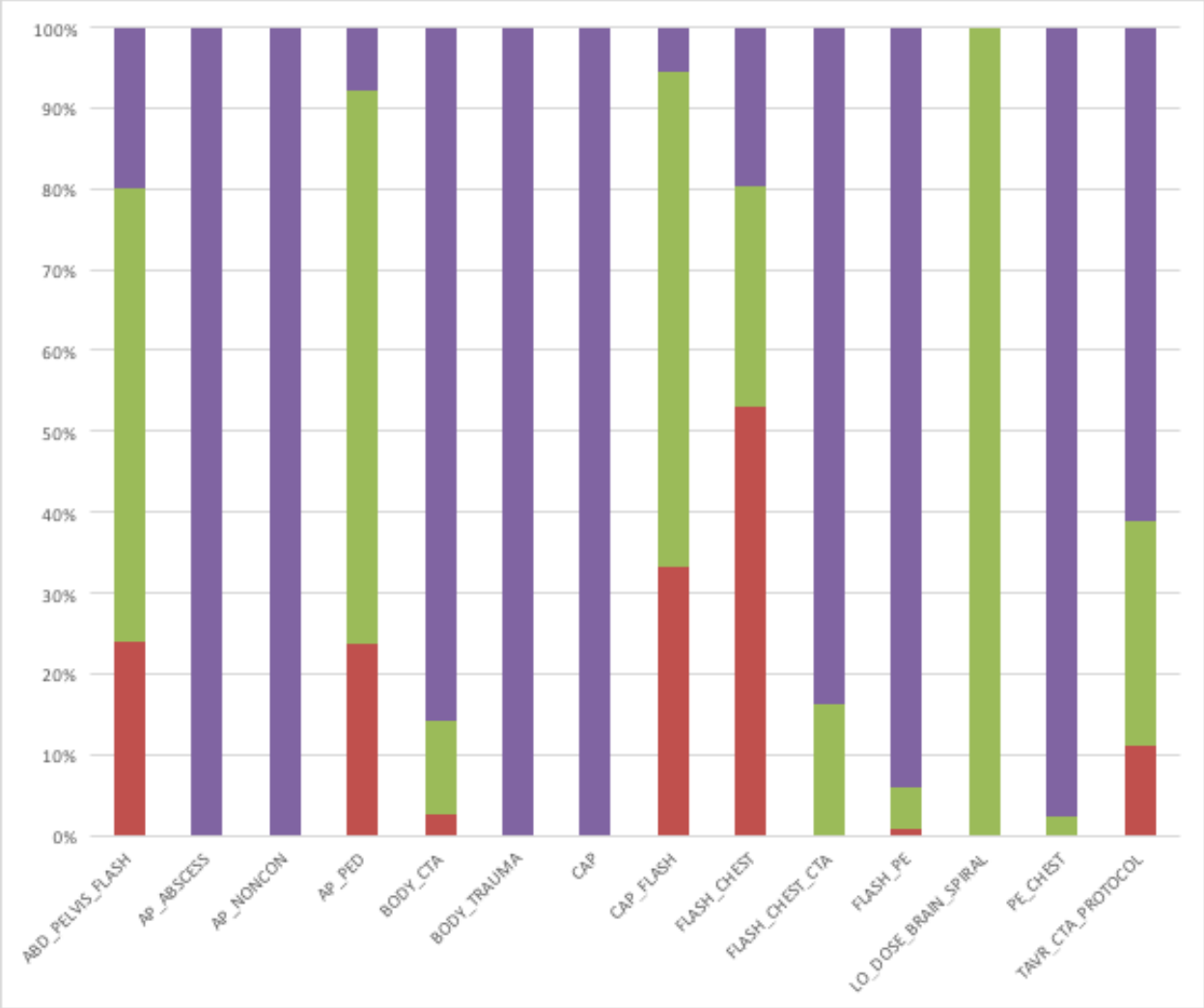
Figure 6(b)

Figure 6: (a) Plot of mean dose for CT urograms performed at PSUMC in 2014 (baseline period) stratified by CT scanner. This information led to an adjustment of the urogram protocol on scanner CT3 to bring dose into line with the other three scanners. (b) Plot of mean dose for CT urograms performed at PSUMC in 2015 (post-intervention) stratified by CT scanner – note

decrease of mean dose for studies performed on CT3 from 36 to 22 mSv. *Scanner CT2 was updated shortly after the intervention to a newer machine, allowing urograms to be performed.



7(a)



7(b)

Figure 7: (a) Plot of kVp used for several common CT examinations performed at PSUMC in 2014 (baseline period). (b) 2015 (intervention period). Purple = 120 kVp, Green = 100 kVp, Red = 80 kVp, Blue = 70 kVp. Demonstration that many scan protocols were performed only at 120 kVp, which was not taking advantage of the automated kVp adjustment software built into many of their scanners, the use of which can result in considerable dose savings. Following the intervention, some protocols have more scans are performed at lower kVp (For example for protocol ABD_PELVIS_FLASH, 80% of scans are performed at <120 kVp after intervention, compared to 63% before), while others have fewer (e.g. TAVR_CTA_PROTOCOL, 38% vs. 52%), however overall more scans were performed at lower kVp given addition of new low kVp protocols such as CAP_FLASH

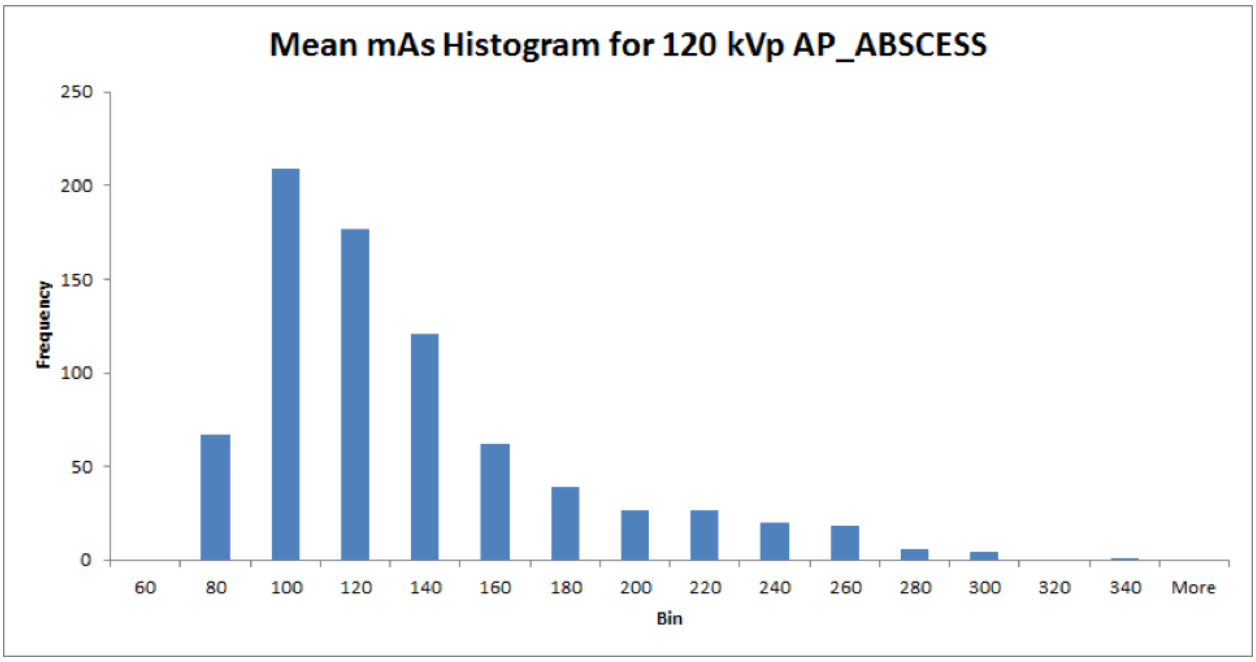


Figure 8: Plot of mean mAs for all CTs performed at PSUMC in 2014 using the Abdomen/Pelvis_Abscess protocol (this is the routine AP scan used at PSUMC). As shown in figure 6, all of these exams were performed at 120 kVp. The site reported that they did not use automated kVp adjustment because they believed that very few of their scans could be performed at lower kVp (and thus lower dose) because of limitations of the tube current output of their scanners. This plot demonstrated that most of these exams are performed at low mAs values (<150 mAs), which is much less than the maximum tube capacity for their scanners, meaning that a majority of these scans could actually be performed at lower kVp and thus lower radiation dose. There was also a concern that use of automated kVp adjustment would result in many exams (of larger patients) being performed at a higher kVp (thus with higher dose), however this plot shows that very few of their exams are performed near the tube current limit of their scanners, thus very few would have kVp adjusted upwards. Presentation of this data resulted in meetings between medical physics and radiologists in several sections at PSUMC to discuss implementation of low kVp scanning

Analysis of effects of technologist interventions

On site training was completed for Geisinger and PSUMC Hershey sites in late 2014. Because of delays in obtaining access to GE manufacturer specific dose training videos, the other intervention arm did not begin until April 2015, therefore we will consider the interventions to be on-site technologist training vs. no technologist intervention. Figure 9 shows overall mean dose levels for the Geisinger sites pre vs. post intervention. The overall trend is for a slight increase in dose, without any relationship to on-site training.

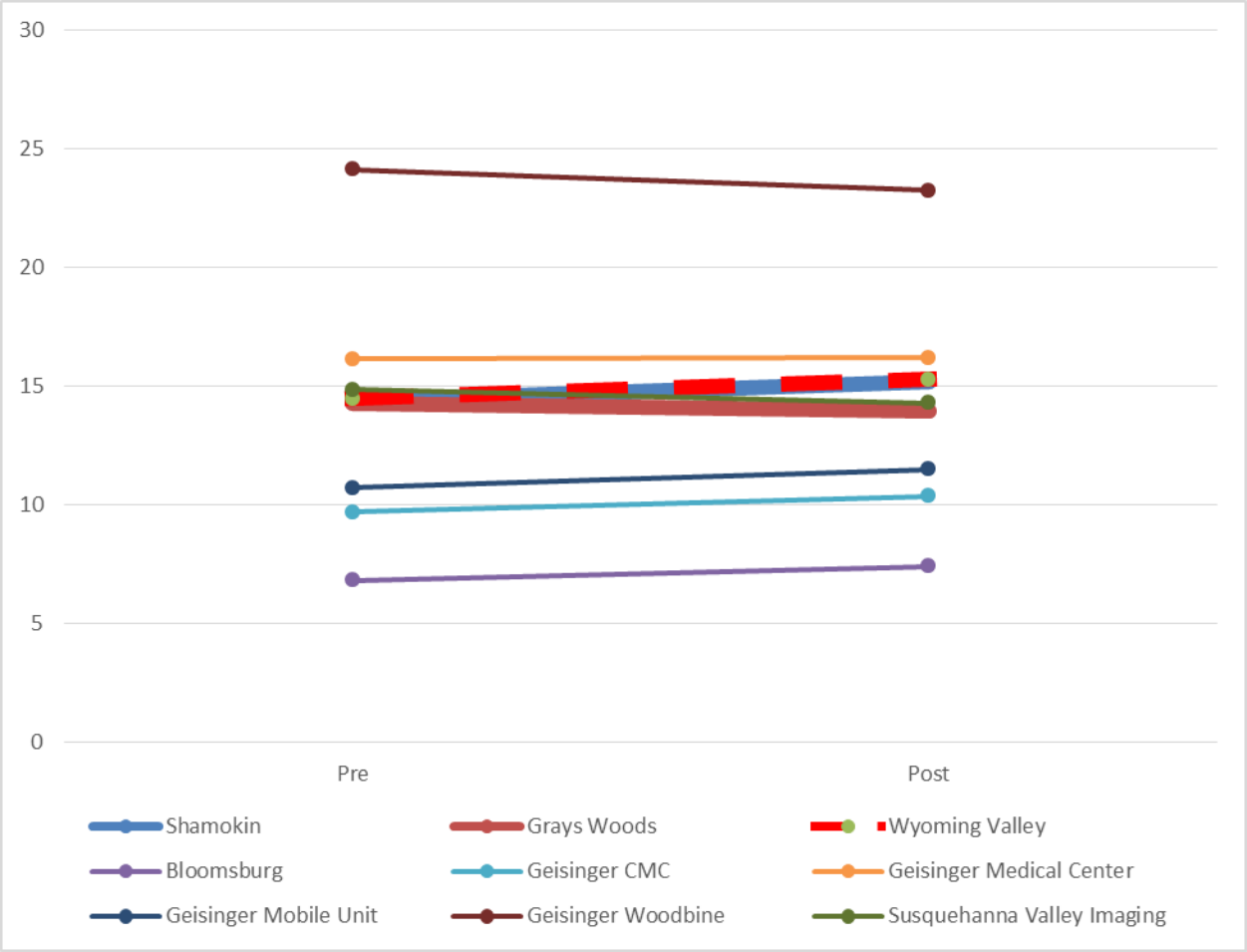


Figure 9: Plot of changes in overall mean dose per site for Geisinger sites from before to after interventions. Thicker lines denote sites that underwent on-site training (Shamokin, Grays Woods, and Wyoming Valley – note Shamokin doses were nearly equivalent to Wyoming Valley so Wyoming Valley line is dashed). Thinner lines represent sites that did not have on-site training. The overall trend is a slight increase in dose over time (5 sites vs. 4 with slight decreases), with no discernable pattern related to on-site training.

Our hypotheses included that on-site technologist training would result in up to a 25% reduction in CTDIvol for the examinations that we were analyzing. Figure 10 shows CTDIvol trend data for all of the Geisinger sites for pulmonary embolism CT, which one covered extensively in the on-site training, including recommendations for protocol modification and tips for technologists to optimize acquisitions to lower dose. Note the decrease in dose over time at Geisinger Wyoming Valley, which underwent on-site training, from 19.7 to 14.4 mGy, a 27% decrease. Evaluation of the individual exam records reveals that after the on-site training, this site divided its PE studies into two protocols, for average and large-sized patients. The usual PE protocol was reduced from 120 to 100 kVp (this would result in 25-30% dose reduction for each patient scanned at 100 kVp) and the pulmonary artery localizer images technique was reduced by 80% (250 to 50 mAs). CTDIvol at the other sites that had on-site training (Shamokin and Grays Woods – also called Geisinger Medical Group) did not change after the intervention. Review of cases from those sites shows that despite implementation of two different PE protocols for different sized patients, a much smaller percentage of the routine protocol cases were performed at 100 kVp compared to 120 kVp than at Wyoming Valley. This finding demonstrates that even though the same protocol is employed at different sites, differences in implementation by the technologists (in this case which sized patients to scan at 100 vs. 120 kVp) can have an important effect on doses.

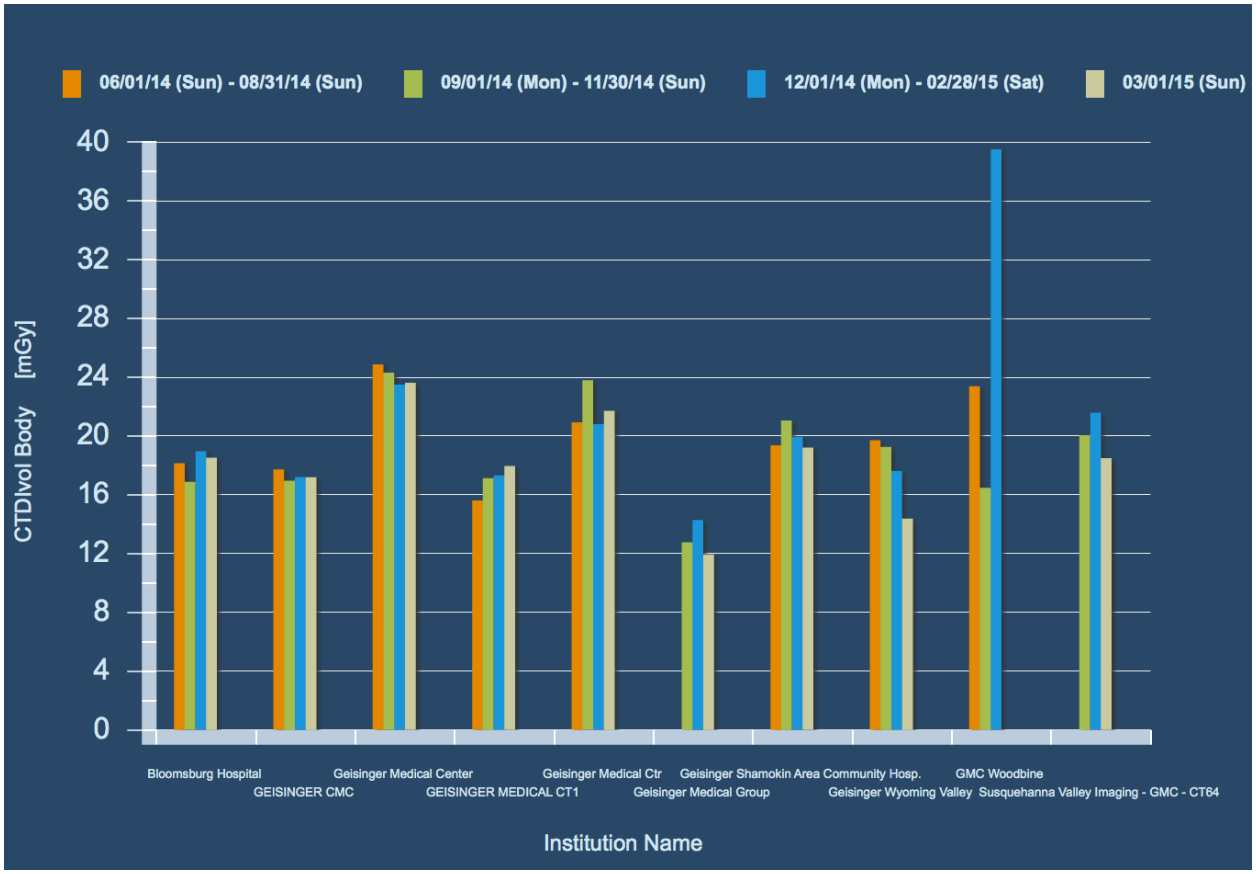


Figure 10: Trend in CTDIvol over time at Geisinger sites for pulmonary embolism protocol CTs. Note a 27% decrease from before to after the on-site training at Geisinger Wyoming Valley, related mostly to implementation of size-based kVp reduction.

During the baseline data analysis, we noted very high doses for ECG-gated CT angiography exams at some of the Geisinger sites. Figure 11 was part of the presentation given to the technologists at Geisinger Wyoming Valley and shows doses in mSv for gated CT angiography studies across all sites, with doses from their site being the highest of any of the sites in the study. We reviewed causes for this, and specifically reasons for higher doses there compared to other Geisinger sites and found that some of the difference was related to longer scan lengths at this site compared to others, described above as "overscanning".

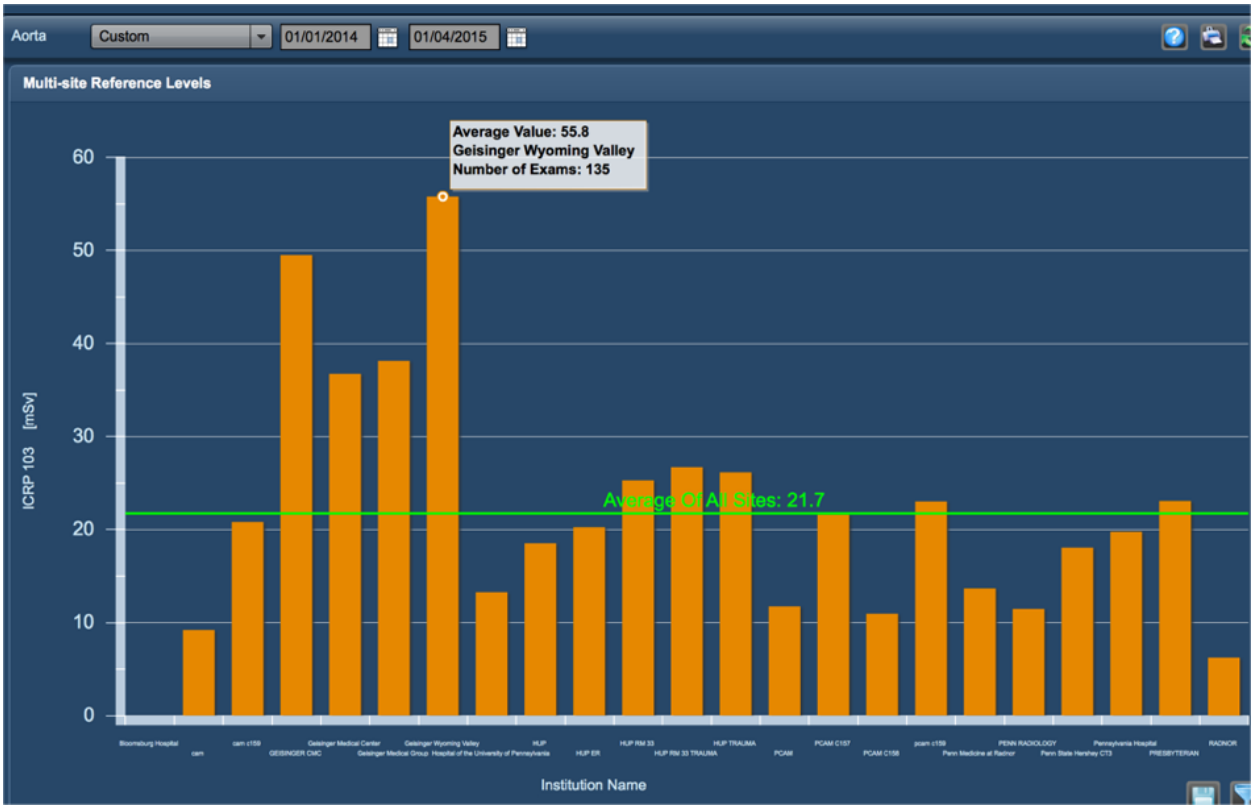


Figure 11: Mean doses for ECG-gated CT angiography studies demonstrating that Wyoming Valley had the highest mean dose of any site. Analysis of their exams revealed that some of this difference was related to overscanning, i.e. scanning more of the body than was needed for the study – either scanning down into the thighs for exams including the pelvis, or up into the neck for exams including the chest.

Figure 12 shows trend data for ECG-gated CTA studies at the Geisinger sites that perform these types of exams. While there was no change in CTDIvol at Wyoming Valley after the on-site training (a), mean effective dose did decrease by 25% (b), related to a corresponding decrease in average scan length (c).

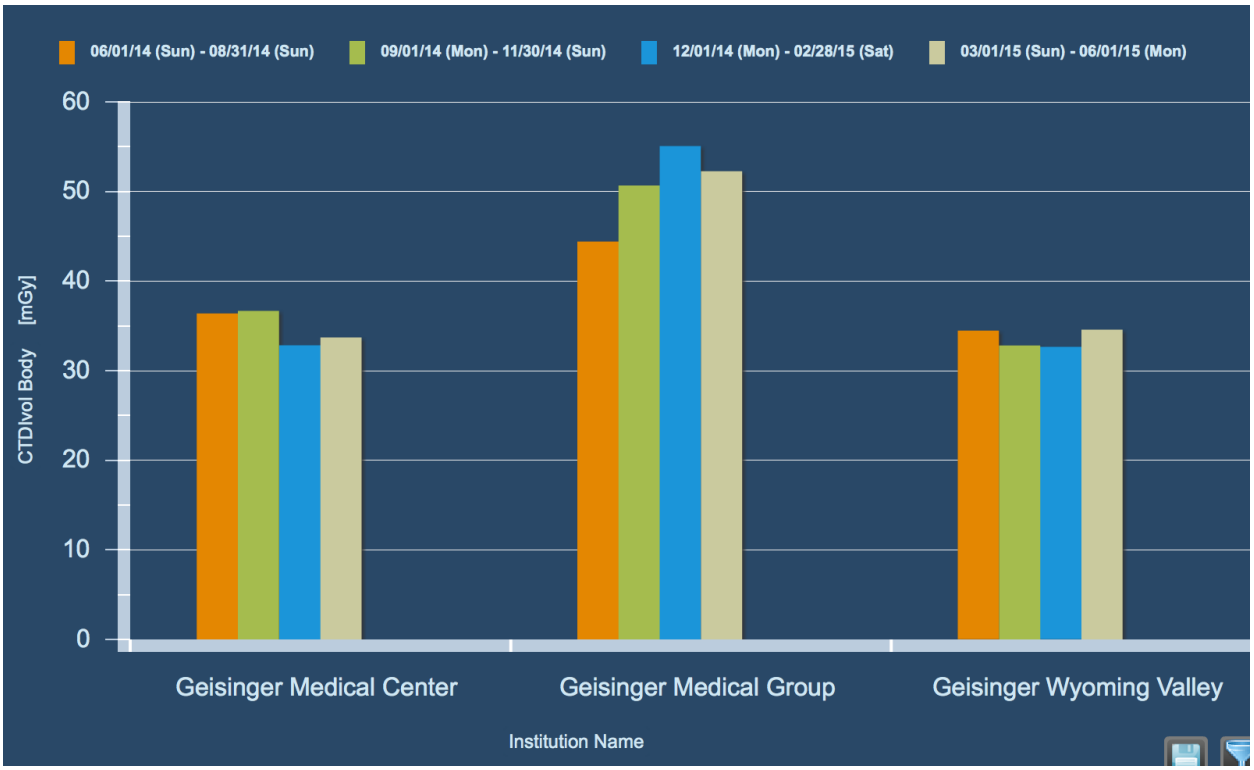


Figure 12(a)

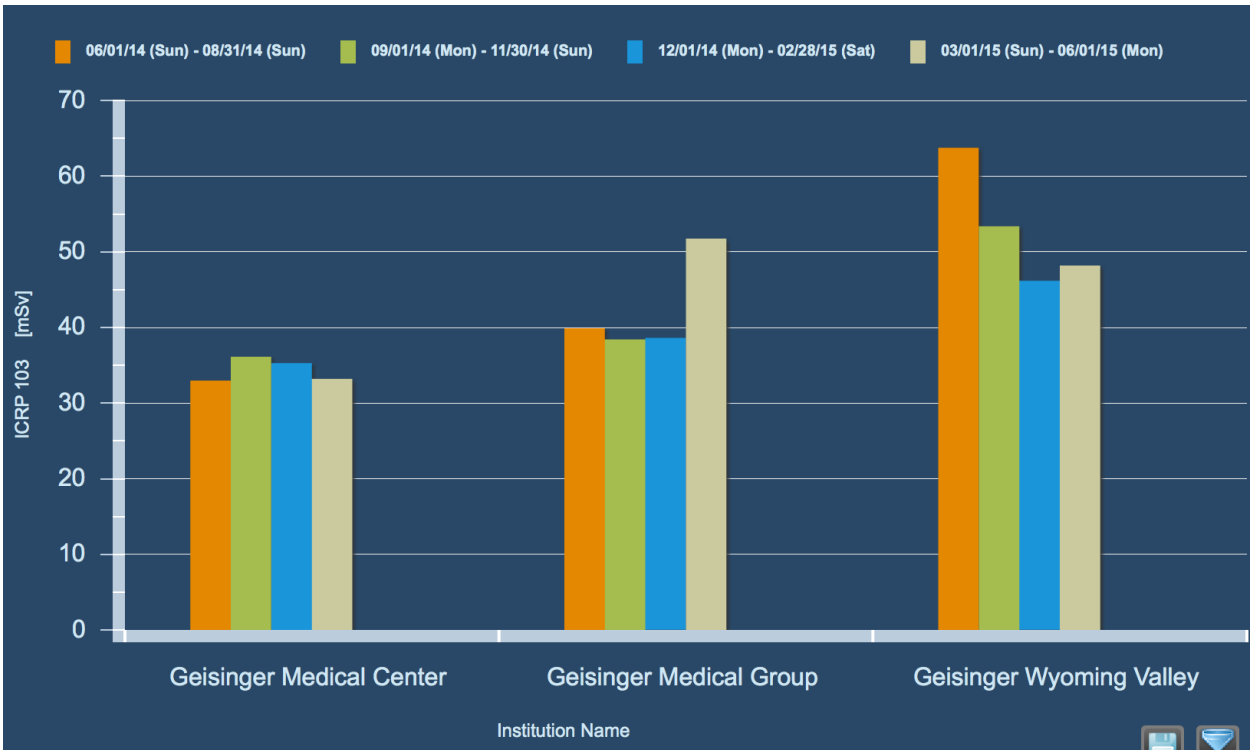


Figure 12 (b)

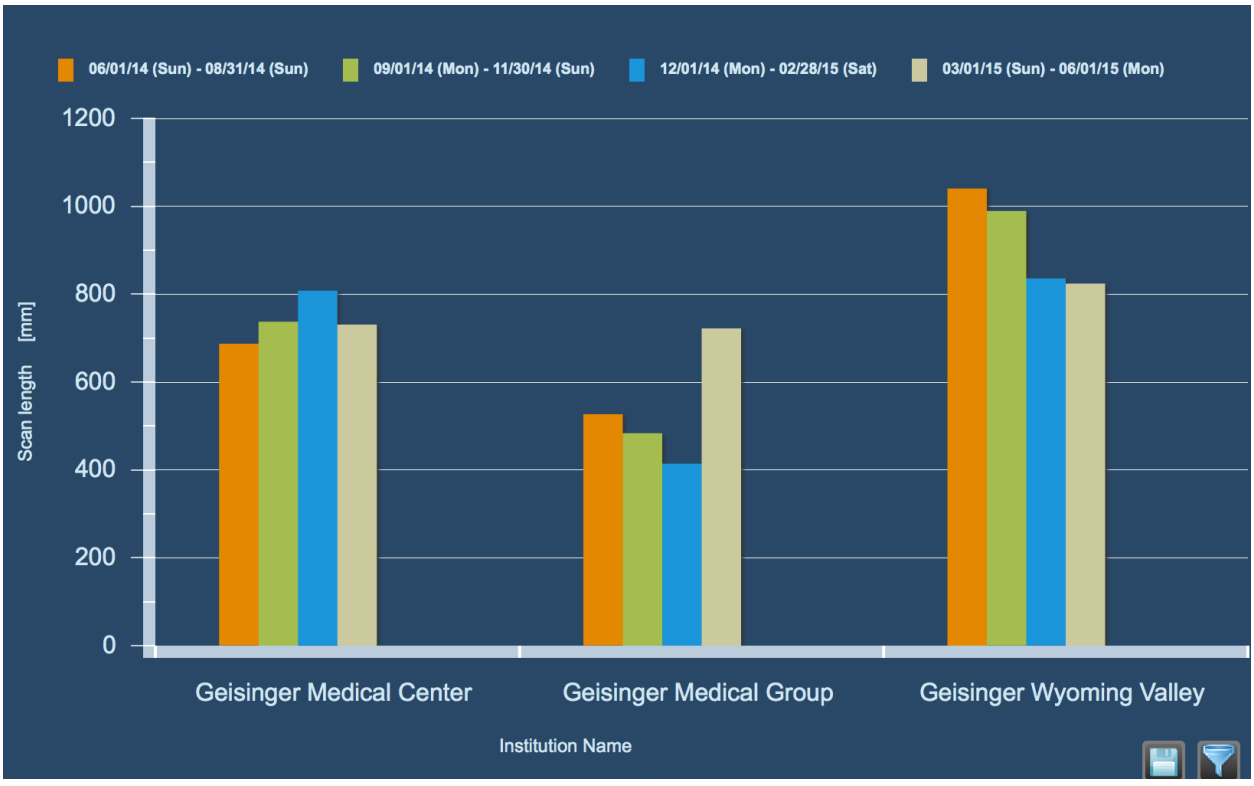


Figure 12(c)

More modest changes were seen in CTDIvol at Hershey. Figure 13 shows changes in CTDIvol for pulmonary embolism studies, with up to 20% reductions; however, the principal change seems to be harmonizing of the doses between the scanners in the hospital (CT3, CT4, and CT5). Note that CT2 was not yet installed when the on-site training occurred, however it would seem that the protocol on that scanner is not in line with those on the other scanners.

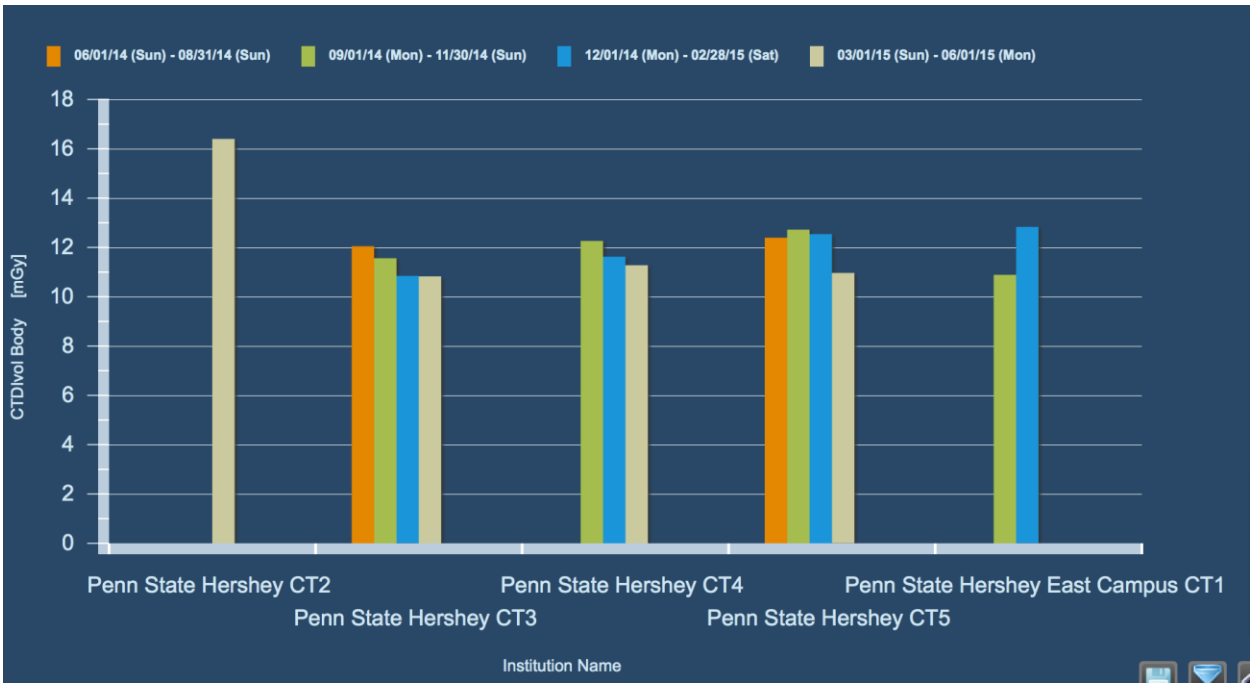


Figure 13: Trend in CTDIvol for pulmonary embolism CT at PSUMC

Analysis of the effects of the on-site training will continue. On-site training was conducted at Penn and Penn Community Radiology sites in spring 2015. This training and viewing of the on-line material for those sites randomized to that were delayed by the move of trauma from HUP to Penn Presbyterian in January 2015, installation of new equipment at HUP and PPMC in late 2014 and early 2015, and a change in the radiology information system used throughout Penn in early 2015. These dramatic changes in the environment for the CT techs led those sites to delay implementation of the interventions for this project.

18. Extent of Clinical Activities Initiated and Completed. Items 18(A) and 18(B) should be completed for all research projects. If the project was restricted to secondary analysis of clinical data or data analysis of clinical research, then responses to 18(A) and 18(B) should be "No."

18(A) Did you initiate a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

_____Yes

__X___No

18(B) Did you complete a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

_____Yes
___X__No

If "Yes" to either 18(A) or 18(B), items 18(C) – (F) must also be completed. (Do NOT complete 18(C-F) if 18(A) and 18(B) are both "No.")

18(C) How many hospital and health care professionals were involved in the research project?

_____Number of hospital and health care professionals involved in the research project

18(D) How many subjects were included in the study compared to targeted goals?

_____Number of subjects originally targeted to be included in the study
_____Number of subjects enrolled in the study

Note: Studies that fall dramatically short on recruitment are encouraged to provide the details of their recruitment efforts in Item 17, Progress in Achieving Research Goals, Objectives and Aims. For example, the number of eligible subjects approached, the number that refused to participate and the reasons for refusal. Without this information it is difficult to discern whether eligibility criteria were too restrictive or the study simply did not appeal to subjects.

18(E) How many subjects were enrolled in the study by gender, ethnicity and race?

Gender:
_____Males
_____Females
_____Unknown

Ethnicity:
_____Latinos or Hispanics
_____Not Latinos or Hispanics
_____Unknown

Race:
_____American Indian or Alaska Native
_____Asian
_____Blacks or African American
_____Native Hawaiian or Other Pacific Islander
_____White
_____Other, specify:_____
_____Unknown

18(F) Where was the research study conducted? (List the county where the research study was conducted. If the treatment, prevention and diagnostic tests were offered in more than one county, list all of the counties where the research study was conducted.)

19. Human Embryonic Stem Cell Research. Item 19(A) should be completed for all research projects. If the research project involved human embryonic stem cells, items 19(B) and 19(C) must also be completed.

19(A) Did this project involve, in any capacity, human embryonic stem cells?
_____Yes
_X___ No

19(B) Were these stem cell lines NIH-approved lines that were derived outside of Pennsylvania?
____Yes
____ No

19(C) Please describe how this project involved human embryonic stem cells:

20. Articles Submitted to Peer-Reviewed Publications.

20(A) Identify all publications that resulted from the research performed during the funding period and that have been submitted to peer-reviewed publications. Do not list journal abstracts or presentations at professional meetings; abstract and meeting presentations should be listed at the end of item 17. **Include only those publications that acknowledge the Pennsylvania Department of Health as a funding source** (as required in the grant agreement). List the title of the journal article, the authors, the name of the peer-reviewed publication, the month and year when it was submitted, and the status of publication (submitted for publication, accepted for publication or published.). Submit an electronic copy of each publication or paper submitted for publication, listed in the table, in a PDF version 5.0.5 (or greater) format, 1,200 dpi. Filenames for each publication should include the number of the research project, the last name of the PI, and an abbreviated title of the publication. For example, if you submit two publications for Smith (PI for Project 01), one publication for Zhang (PI for Project 03), and one publication for Bates (PI for Project 04), the filenames would be:

Project 01 – Smith – Three cases of isolated
Project 01 – Smith – Investigation of NEB1 deletions
Project 03 – Zhang – Molecular profiling of aromatase
Project 04 – Bates – Neonatal intensive care

If the publication is not available electronically, provide 5 paper copies of the publication.

Note: The grant agreement requires that recipients acknowledge the Pennsylvania Department of Health funding in all publications. Please ensure that all publications listed

acknowledge the Department of Health funding. If a publication does not acknowledge the funding from the Commonwealth, do not list the publication.

Title of Journal Article:	Authors:	Name of Peer-reviewed Publication:	Month and Year Submitted:	Publication Status (check appropriate box below):
1. None				☐Submitted ☐Accepted ☐Published

20(B) Based on this project, are you planning to submit articles to peer-reviewed publications in the future?

Yes_____X____ No_____

If yes, please describe your plans:

Several publications are planned including:

1. Description of large degree of variability in doses for most common exams across sites
2. Analysis of the effect of level of technology on doses
3. Analysis of effect of technologist training on doses

These publications would be most appropriate for general radiology journals such as Radiology and Journal of the American College of Radiology.

21. Changes in Outcome, Impact and Effectiveness Attributable to the Research Project. Describe the outcome, impact, and effectiveness of the research project by summarizing its impact on the incidence of disease, death from disease, stage of disease at time of diagnosis, or other relevant measures of outcome, impact or effectiveness of the research project. If there were no changes, insert "None"; do not use "Not applicable." Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

None.

22. Major Discoveries, New Drugs, and New Approaches for Prevention Diagnosis and Treatment. Describe major discoveries, new drugs, and new approaches for prevention, diagnosis and treatment that are attributable to the completed research project. If there were no major discoveries, drugs or approaches, insert "None"; do not use "Not applicable." Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

None.

23. Inventions, Patents and Commercial Development Opportunities.

23(A) Were any inventions, which may be patentable or otherwise protectable under Title 35 of the United States Code, conceived or first actually reduced to practice in the performance of work under this health research grant? Yes_____ No___X_____

If "Yes" to 23(A), complete items a – g below for each invention. (Do NOT complete items a - g if 23(A) is "No.")

a. Title of Invention:

b. Name of Inventor(s):

c. Technical Description of Invention (describe nature, purpose, operation and physical, chemical, biological or electrical characteristics of the invention):

d. Was a patent filed for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?
Yes_____ No____

If yes, indicate date patent was filed:

e. Was a patent issued for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?
Yes_____ No____
If yes, indicate number of patent, title and date issued:
Patent number:
Title of patent:
Date issued:

f. Were any licenses granted for the patent obtained as a result of work performed under this health research grant? Yes_____ No____

If yes, how many licenses were granted?_____

g. Were any commercial development activities taken to develop the invention into a commercial product or service for manufacture or sale? Yes___ No____

If yes, describe the commercial development activities:

23(B) Based on the results of this project, are you planning to file for any licenses or patents, or undertake any commercial development opportunities in the future?

Yes_____ No____X_____

If yes, please describe your plans:

24. Key Investigator Qualifications. Briefly describe the education, research interests and experience and professional commitments of the Principal Investigator and all other key investigators. In place of narrative you may insert the NIH biosketch form here; however, please limit each biosketch to 1-2 pages.

PEOPLE AND PLACES
PROFESSIONAL PROFILE/BIOSKETCH

NAME Mitchell D. Schnall, M.D., Ph.D.	POSITION TITLE Professor of Radiology
eRA COMMONS USER NAME schnallm	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education,*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Pennsylvania	B.A.	1981	Physics
University of Pennsylvania	M.D.	1986	Medicine
University of Pennsylvania	Ph.D.	1986	Biophysics

B. Positions and Honors

Positions and Employment

2012 Eugene P. Pendergrass Professor of Radiology, of Pennsylvania School of Medicine, Phila.
2008- American College of Radiology Imaging Network (ACRIN) –Chair
2004-08 American College of Radiology Imaging Network (ACRIN) – Deputy Chair
2002 Professor of Radiology
2001 Matthew J. Wilson Professor of Research Radiology
1998 Associate Professor with tenure
1994 Associate Professor, Department of Radiology, University of Pennsylvania School of Medicine
1991 Assistant Professor, Department of Radiology, University of Pennsylvania School of Medicine, Phila.
1987 Assistant Instructor, Department of Radiology, University of Pennsylvania School of Medicine, Phila.
1987 Radiology Resident, Department of Radiology, Hospital of the University of Pennsylvania, Phila., PA
1986-87 Medical Internship, Lankenau Hospital, Wynnewood, PA
1982-86 NIH Medical Scientist Training Program Fellowship, University of Pennsylvania, Philadelphia, PA

Other Experience and Professional Memberships

1987- Radiological Society of North America
1990- International Society for Magnetic Resonance in Medicine
1995- American College of Radiology
2003- American Association for Cancer Research
2006- The American Society for Clinical Investigation (ASCI)
2007- RSNA Clinical Trials Methodology Workshop – Organizer
2009-2013 Member – Clinical Trials & Translational Research Advisory Committee (CTAC) of the NCI

Honors

1979-Benjamin Franklin Scholar, University of Pennsylvania; **1980-University Scholar, University of PA;** 1981-Phi Beta Kappa; 1982-William E. Stephens Physics Award, University of Pennsylvania; 1982-Summa Cum Laude graduate, University of Pennsylvania; 1985-Alpha Omega Alpha Medical Honor Society; 1986-Sigma Xi Outstanding Science PhD Thesis Award, University of Pennsylvania; 1989-Chief Resident, Department of Radiology, University of Pennsylvania; 1989-Outstanding Paper Award, Society of Uroradiology; 1992-Lauterber Award, Society of Computed Body Tomography and MR; 1992-**RSNA Scholars Award;** 1999-Luigi Mastroianni Clinical Innovator Award; 2008-The American Society for Clinical Investigation (ASCI); 2009-The Association of American Physicians (AAP); 2010-Fellow in the American College of Radiology; 2012-Elected to the IOM

C. Selected Peer-reviewed Publications

Lehman CD, Gatsonis C, Kuhl CK, Hendrick RE, Pisano ED, Hanna L, Peacock S, Smazal SF, Maki DD, Julian TB, DePeri ER, Bluemke DA, **Schnall MD**. ACRIN Trial 6667 Investigators Group. MRI evaluation of the contralateral breast in women with recently diagnosed breast cancer. N Engl J Med. 2007 Mar 29;356(13):1295-303.

Kumar R, Zhuang H, **Schnall M**, Conant E, Damia S, Weinstein S, Chandra P, Czerniecki B, Alavi A. FDG PET positive lymph nodes are highly predictive of metastasis in breast cancer. Nucl Med Commun. 2006 Mar;27(3):231-6.

Solin LJ, Orel SG, Hwang WT, Harris EE, **Schnall MD**. Relationship of breast magnetic resonance imaging to outcome after breast-conservation treatment with radiation for women with early-stage invasive breast carcinoma or ductal carcinoma in situ. J Clin Oncol. 2008 Jan 20;26(3):386-91. (PMID: 18202414)

Boo-Kyung H, **Schnall MD**, Orel SG, Rosen M. Outcome of MRI-guided breast biopsy. AJR 2008; 191:1-7

Dorfman GS, Sullivan DC, **Schnall MD**, Matrisian LM; for the Translational Research Working Group. The Translational Research Working Group Developmental Pathway for Image-Based Assessment Modalities. Clin Cancer Res. 2008 Sep 15;14(18):5678-5684. Weinstein SP, Localio AR, Conant EF, Rosen M, Thomas KM, **Schnall MD**. Multimodality screening of high-risk women: a prospective cohort study. J Clin Oncol, Dec. 2009; 27(36): 6124-8. PMCID: PMC2793033

Busch DR, Guo W, Choe R, Durduran T, Feldman MD, Mies C, Rosen MA, **Schnall MD**, Czerniecki BJ, Tchou J, DeMichele A, Putt ME, Yodh AG. Computer aided automatic detection of malignant lesion in diffuse optical mammography. Med Phys, Apr 2010; 37(4): 1840-9. PMCID: PMC2864673

Weinstein SP, Hanna LG, Gatsonis C, **Schnall MD**, Rosen MA, Lehman CD. Frequency of malignancy seen in probably benign lesions of contrast-enhanced breast MR imaging: findings from ACRIN 6667. Radiology, Jun 2010; 255(3): 731-7. PMCID: PMC2887932

National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med, August 4, 2011; 365(5); 395-409 (PMID: 21714641)

Hylton NM, Blume JD, Bernreuter WK, Pisano ED, Rosen MA, Morris EA, Weatherall PT, Lehman CD, Newstead GM, Polin S, Marques HS, Esserman LJ, **Schnall MD**; ACRIN 6657 Trial Team and I-SPY 1 TRIAL Investigators. Locally advanced breast cancer: MR imaging for prediction of response to neoadjuvant chemotherapy--results from ACRIN 6657/I-SPY TRIAL. Radiology. 2012 Jun;263(3):663-72. PMCID: PMC3359517

BIOGRAPHICAL SKETCH

NAME Harold I. Litt	POSITION TITLE Chief, Cardiovascular Imaging Section Associate Professor of Radiology and Medicine
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Harvard College, Cambridge, MA	A.B	1988	Physics/Biophysics
Harvard Graduate School of Arts and Sciences	A.M.	1988	Physics
SUNY at Buffalo School of Med & Biomed Sci	M.D.	1996	Medicine
SUNY at Buffalo School of Med & Biomed Sci	Ph.D.	1996	Biophysical Sciences

B. Positions and Honors

Positions and Employment

1996	Guest Researcher, Unit on Brain Imaging and Computing, Laboratory for Neurosciences, National Institute on Aging, National Institutes of Health, Bethesda, MD
7/1996-6/1997	Intern in Medicine and Clinical Fellow, Department of Medicine, Mount Auburn Hospital-Harvard Medical School, Cambridge, MA
7/1997-6/2001	Resident in Radiology and Assistant Instructor in Radiology, University of Pennsylvania School of Medicine, Philadelphia, PA
7/2001-6/2002	Fellow in Cardiothoracic Radiology and Clinical Instructor, Dept of Radiology, University of California San Francisco School of Medicine
7/2002-5/2011	Assistant Professor of Radiology, University of Pennsylvania School of Medicine
7/2002-5/2003	Associate Director of Cardiovascular Imaging, Chief of Cardiac CT, Department of Radiology,University of Pennsylvania Medical Center
6/2003-	Chief, Cardiovascular Imaging Section, Department of Radiology, University of Pennsylvania Medical Center
5/2005-	Assistant Professor of Radiology in Medicine, University of Pennsylvania School of Medicine
7/2005-	Director, Center for Advanced Computed Tomography Imaging Sciences, Department of Radiology, University of Pennsylvania Medical Center
6/2011-	Associate Professor of Radiology, Associate Professor of Radiology in Medicine, Perelman School of Medicine of the University of Pennsylvania

Other Experience and Professional Memberships

Honors and Awards:

4/1992	The Future of Medicine Award, Eastern Student Research Forum
5/1992	Roche Laboratories Award for Excellence in Clinical Research, Second Prize, National Student Research Forum
9/1996	Young Investigator Award, Third International Conference on Quantification of Brain Function with PET
11/1998	Radiological Society of North America Resident Research Trainee Prize
6/2001	Baum-Laufer Award for Excellence in Service to the Penn Radiology Residency
12/2009	Journal of Thoracic Imaging Editors' Recognition Award for Distinction in Reviewing 2009
10/2011	Elected Fellow, North American Society of Cardiovascular Imaging
11/2011	Elected Fellow, American Heart Association

C. Selected Peer-reviewed Publications (Selected from 75 peer-reviewed publications)

Most relevant to the current application

1. Litt H, Brody A, Spangler R, Scott P. Application of Nonlinear System Identification to Magnetic Resonance Imaging and Computed Tomography. IEEE Engineering in Medicine & Biology Conference 1995:1389-1390.
2. Harris EE, Correa C, Hwang WT, Liao J, Litt HI, Ferrari VA, Solin LJ. Late cardiac mortality and morbidity in early stage breast cancer patients after breast conservation treatment. Journal of Clinical Oncology, 1 Sept 2006; 24(25).
3. Hollander JE, Chang AM, Shofer FS, McCusker CM, Baxt WG, Litt HI. Coronary Computerized Tomography for Rapid Discharge of Low Risk Patients with Potential Acute Coronary Syndromes. Annals of Emergency Medicine 2009 March;53(3):295-304
4. Luaces M, Akers S, Litt H. Low kVp Imaging for Dose Reduction in Dual-Source Cardiac CT. International Journal of Cardiovascular Imaging, (2009) 25:165–175.
5. Sundar H, Litt H, Shen D. Estimating myocardial motion by 4D image warping. Pattern Recognition, 2009 November;42(11):2514-2526.
6. Sheehan FH, Kilnerb PJ, Sahn DJ, Vick GW, Stout KK, Shupin GED, Helbing WA, Lewin M, Shurman AJ, Valsangiacomo-Buechel E, Litt HI, Waiss MP. Accuracy of Knowledge Based Reconstruction for Measurement of Right Ventricular Volume and Function in Patients with Tetralogy of Fallot. American Journal of Cardiology, 2010 Apr 1;105(7):993-9.
7. Wilson JM, Sanzari JK, Diffenderfer ES, Yee SS, Seykora JT, Maks C, Ware JH, Litt HI, Reetz JA, McDonough J, Weissman D, Kennedy AR, Cengel KA. Acute biological effects of simulating the whole-body radiation dose distribution from a solar particle event using a porcine model. Radiat Res. 2011 Nov;176(5):649-59.
8. Litt HI, Gatsonis C, Snyder B, Singh H, Miller CD, Entrikin DW, Leaming JM, Gavin LJ, Pacella CB, Hollander JE. CT Angiography for Safe Discharge of Patients with Possible Acute Coronary Syndromes. N Engl J Med. 2012 April 12; 366(15):1393-1403